UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION This document relates to: *State of Alabama v. Purdue Pharma, L.P., et al.*, Case No. 18-OP-45236	MDL 2804 Hon. Dan Aaron Polster

BRIEF OF AMICI STATES OF CONNECTICUT, NORTH CAROLINA, PENNSYLVANIA, ARIZONA, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, HAWAI'I, IDAHO, ILLINOIS, IOWA, LOUISIANA, MAINE, MARYLAND, MICHIGAN, MINNESOTA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NEW YORK, NORTH DAKOTA, OHIO, OREGON, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, TEXAS, VIRGINIA, AND WASHINGTON IN OPPOSITION TO MCKESSON'S MOTION TO DISMISS THE STATE OF ALABAMA'S FIRST AMENDED COMPLAINT

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The State of Connecticut, the State of North Carolina, the Commonwealth of Pennsylvania, the State of Arizona, the State of Delaware, the District of Columbia, the State of Florida, the State of Hawaii, the State of Idaho, the State of Illinois, the State of Iowa, the State of Louisiana, the State of Maine, the State of Maryland, the State of Michigan, the State of Minnesota, the State of Mississippi, the State of Montana, the State of Nebraska, the State of Nevada, the State of New Mexico, the State of New York, the State of North Dakota, the State of Ohio, the State of Oregon, the State of Rhode Island, the State of South Carolina, the State of Tennessee, the State of Texas, the Commonwealth of Virginia, and the State of Washington respectfully submit this *amici curiae* brief in support of Alabama's opposition to McKesson's motion to dismiss. States have compelling interests in protecting the health, safety, and welfare of their citizens. State attorneys general routinely promote these interests by enforcing consumer protection statutes and other state laws. In doing so, they often rely on statutory authorization or *parens patriae* authority to prevent or remedy harm to the health and well-being of their residents. *Alfred L. Snapp & Son, Inc. v. Puerto Rico ex rel. Barez*, 458 U.S. 592, 607 (1982).

Opioid abuse and addiction are fueling the deadliest drug crisis in American history. The Amici States' attorneys general represent communities with some of the highest opioid and heroin abuse rates in the country. These abuses have inflicted catastrophic injury to the health and welfare of their residents. Millions of the residents of the Amici States are now addicted to prescription opioids and tens of thousands die annually from overdoses.[1] Each of the States—through various public health programs and law enforcement efforts—has also borne substantial costs to mitigate and respond to the opioid epidemic.

[1] Centers for Disease Control and Prevention, *Opioid Overdose: Understanding the Epidemic* (2017), *available at* https://www.cdc.gov/drugoverdose/epidemic/ (last visited Aug. 3, 2018).

In response to the crisis, more than 40 state attorneys general, including the Attorney General of Alabama, formed a coalition to investigate opioid distributors. On September 18, 2017, the multistate group requested documents and information related to distribution practices from three drug distributors, including McKesson.[2] This investigation continues, with the multistate group presently receiving and reviewing productions from the distributors and opioid distribution data made available through the Court's ARCOS Protective Order. Additionally, like Alabama, several Amici States have filed lawsuits against McKesson and other distributors.

INTRODUCTION

There is no doubt—and indeed, McKesson does not dispute—that prescription opioids are widely diverted from legitimate distribution channels to illegal ones. The sheer volume of diverted opioids has wrought havoc throughout the Amici States and has plagued Amici States' communities. There is a direct correlation between the sale and distribution of opioids and opioid-induced deaths and hospitalizations.[3]

McKesson—controlling approximately one-third[4] of the drug distribution market—claims that it bears no responsibility for the opioid epidemic because it is merely the truck driver between a manufacturer that makes the opioid and a pharmacy that stocks the opioid. This claim is belied by the extensive role that massive distribution companies like McKesson actually play in the pharmaceutical industry. But, more importantly for purposes of this brief, McKesson

[2] http://myfloridalegal.com/webfiles.nsf/WF/JMAR-ARBR24/$file/McKesson+Inquiry+Letter.pdf (last visited Aug. 3, 2018).

[3] Andrew Kolodny et al., *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*, 36 Ann. Rev. Pub. Health 559 (2015), *available at* http://www.annualreviews.org/doi/pdf/10.1146/annurev-publhealth-031914-122957 (last visited Aug. 3, 2018).

[4] Company Profile & Description, https://www.mckesson.com/about-mckesson (last visited Aug. 3, 2018).

ignores the distributor's legal duties to prevent diversion and to monitor, detect, investigate, refuse, and report suspicious orders of opioids.

Accordingly, the Amici States urge this Court to deny McKesson's Motion to Dismiss.

ARGUMENT

I. State Laws, Enforced by State Attorneys General, Require Distributors to Prevent Diversion and Detect Suspicious Orders.

Alabama has alleged that McKesson violated its duties under the federal Controlled Substances Act to prevent diversion and detect suspicious orders. *See* Compl. ¶¶ 244-286. Even so, McKesson argues that the federal Controlled Substances Act does not provide states a private right of action against distributors and that state common law does not incorporate distributors' duties under the federal Controlled Substances Act. *See* McKesson Br. at 15-18. But states do not rely solely on the federal Controlled Substances Act to regulate distributors. State laws themselves prohibit opioid distributors from facilitating diversion and from turning a blind eye to suspicious orders.[5] State attorneys general, including the Attorney General of Alabama, are empowered to enforce violations of those laws. McKesson's arguments, therefore, are without merit.

A. State Law Requires that Opioid Distributors Prevent Diversion and Detect Suspicious Orders.

State law imposes freestanding duties upon opioid distributors separate from the federal Controlled Substances Act. The substance of the duties to prevent diversion and detect suspicious orders imposed by state law are generally similar among the states and parallel federal law duties. Accordingly, McKesson is wrong in arguing that "there is no duty under [state] law

[5] This brief discusses only the Uniform Act's duties imposed on distributors. However, it also imposes duties on manufacturers to prevent diversion and detect suspicious orders. *See* Alabama Br. at 35-37.

to halt or report suspicious orders" or that states "may not assert tort claims against McKesson based on its federal regulatory obligation" when those duties parallel state law duties. McKesson Br. at 15.

State regulation of distributors is largely uniform: 48 states (all but New Hampshire and Vermont), the District of Columbia, Puerto Rico, and the U.S. Virgin Islands have adopted a model state statute, the Uniform Controlled Substances Act of 1970 ("Uniform Act").[6] *See* Exhibit A; *see also e.g.*, Ala. Code §§ 20-2-1 to -190.

The Uniform Act requires that every distributor of controlled substances, like opioids, must obtain an annual registration from the appropriate state agency. Uniform Act § 302(a); *see also* Ala. Code § 20-2-51(a). The Uniform Act then requires those registered distributors to follow its substantive requirements. Uniform Act § 302(b); *see also* Ala. Code § 20-2-51(b).

The Uniform Act imposes substantive duties to prevent diversion and detect suspicious orders in two ways. First, the Uniform Act conditions the lawful registration of distributors on the "maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels," and "the existence in the applicant's establishment of effective controls against diversion." Uniform Act § 303(a)(1), (4); *see also* Ala. Code § 20-2-52(a)(1), (4). Second, the Uniform Act specifically grants to third parties (including state agencies and officials) the authority to establish regulations policing the distribution of controlled substances in the state. Uniform Act § 301; *see also* Uniform Act prefatory note ("The Uniform Act updates and improves existing State laws and insures

[6] This count is based on the "table of jurisdictions wherein either the 1970, 1990, or 1994 versions of the act or a combination thereof has been adopted" available in Westlaw.

legislative and administrative flexibility to enable the States to cope with both present and future drug problems."); Ala. Code § 20-2-50(a).

Many states have used their regulatory powers under the Uniform Act to promulgate regulations related to diversion and suspicious orders. In approximately half of the states, these regulations are verbatim, or nearly verbatim, copies of Drug Enforcement Administration ("DEA") regulations related to diversion and suspicious orders. One such regulation that states have implemented as a matter of state law[7] requires explicitly that distributors "provide effective controls and procedures to guard against . . . diversion of controlled substances." 21 C.F.R. § 1301.71(a).[8] Another such regulation that states have implemented as a matter of state law[9]

[7] *See, e.g.*, Ill. Admin. Code tit. 77, § 3100.310(a); 856 Ind. Admin. Code 2-3-30(a); Iowa Admin. Code r. 657-10.13; Kan. Admin Reg. § 68-20-15a(a); La. Admin Code tit. 46, § 2713(a); Md. Code Regs. 10.19.03.12(a)(1); Mo. Code Regs. Ann. tit. 19, § 30-1.031(1); N.J. Admin. Code § 13:45H-2.1(a); N.M. Code R. § 16.19.20.48(a); N.Y. Comp. Codes R. & Regs. tit. 10, § 80.17; 28 Pa. Code § 25.61(a); 216-20-20 R.I. Code R. § 4.7; S.C. Code Ann. Regs. 61-4-401(a); W. Va. Code R. § 15-2-5.1.1; 59-2-3 Wyo. Code R. § 24(a).

[8] Through formal administrative adjudication entitled to deference, *see Auer v. Robbins*, 519 U.S. 452, 461 (1997), the DEA has interpreted this regulation to require each distributor "to perform due diligence on its customers" on an "ongoing [basis] throughout the course of a distributor's relationship with its customer." Masters Pharms., Inc., 80 Fed. Reg. 55,418, 55,477 (DEA Sept. 15, 2015), *petition for review denied*, 861 F.3d 206 (D.C. Cir. 2017). Pursuant to this duty, "a distributor must conduct a reasonable investigation to determine the nature of a potential customer's business before it sells to the customer, and the distributor cannot ignore information which raises serious doubt as to the legality of a potential or existing customer's business practices." *Id*. (alterations and internal quotation marks omitted) (quoting Southwood Pharms., Inc., 72 Fed. Reg. 36,487, 36,498 (DEA July 3, 2007)).

[9] *See, e.g.*, Idaho Admin. Code r. 27-01-01-615(4); 856 Ind. Admin. Code 2-3-33(b); Kan. Admin Reg. § 68-20-15a(c)(2); La. Admin Code tit. 46, § 2715(c)(2); Mo. Code Regs. Ann. tit. 19, § 30-1.032(2); N.J. Admin. Code § 13:45H-2.4(b); N.Y. Comp. Codes R. & Regs. tit. 10, § 80.22; Ohio Admin. Code 4729:9-16(h)(1)(e); Okla. Admin. Code § 475:20-1-5(b); Or. Admin. R. 855-65-10(9); S.C. Code Ann. Regs. 61-4-404(b); W. Va. Code R. § 15-2-5.3; Wis. Admin. Code Phar § 8.10; 59-2-3 Wyo. Code R. § 27(b). Additionally, in recent years several states have codified the requirements of 21 C.F.R. § 1301.74(b) into their statutes. *See, e.g.*, Cal. Bus. & Prof. Code § 4169.1; Conn. Gen. Stat. § 21a-70(*i*); Idaho Code Ann. § 54-1753(7); Tenn. Code Ann. § 53-10-312(c); Va. Code Ann. § 54.1-3435(b).

requires distributors to "design and operate a system to disclose to the [distributor] suspicious orders of controlled substances. The [distributor] shall inform [DEA] of suspicious orders when discovered by the [distributor]. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b). The United States Court of Appeals for the District of Columbia Circuit has held that these regulations require distributors to either 1) report to DEA and refuse to ship each suspicious order or 2) dispel any suspicions based on "actually undertak[ing] [an] investigation" of the order that "must dispel all of the 'red flags' that gave rise to the suspicion that the customer was diverting controlled substances." *Masters Pharms.*, 861 F.3d at 222-23.

Other states have incorporated DEA's anti-diversion and suspicious order requirements into their state law in slightly different ways. Some states have done so by cross-referring to DEA regulations.[10] Alabama, for its part, adopts a slightly more shorthand version of 21 C.F.R. § 1301.74(b) in its regulations. Alabama's regulations state that distributors "shall submit to the Alabama State Board of Pharmacy legible copies of records and reports *required by the Drug Enforcement Administration* concerning increases in purchases or high or unusual volumes

[10] *See, e.g.*, 10A N.C.A.C. 26E.0129(a) ("Any person who . . . distributes . . . any controlled substance shall comply with Part 1301 of Title 21 of the Code of Federal Regulations . . . ."); Wash. Admin. Code 246-879-050(7) ("All applicants for a license as a controlled substances wholesaler must comply with the security requirements as found in 21 CFR . . . 1301.71 through 1301.74 . . . ."). Other states, including Alabama, provide an overarching state law requirement that distributors comply with DEA regulations. *See, e.g.*, Ala. Admin. Code r. 680-X-2-.23(2)(k)(3) ("Wholesale drug distributors shall operate in compliance with applicable Federal . . . laws and regulations."); Minn. R. 6800.1440, subp. 11 ("Wholesale drug distributors who deal in controlled substances . . . shall comply with all applicable . . . Drug Enforcement Administration regulations."); Mont. Admin. R. 24.174.1201(6) (same as Minnesota).

purchased by pharmacies within 30 days."[11] Ala. Admin. Code r. 680-X-3-.05(2) (emphasis added); *see also* Ala. Admin. Code r. 680-X-2-.23(2)(e)(5) (similar requirement).

B. The Uniform Act and Federal Controlled Substances Act Specifically Contemplate State Regulation of Distributors.

As the previous section shows, states have adopted statutes that require the regulation of distributors' diversion and suspicious order mechanisms. The drafters of the Uniform Act and the federal Controlled Substances Act specifically contemplated an independent enforcement role for state law.

The Uniform Act and the federal Controlled Substances Act, which were passed at approximately the same time,[12] were meant to "provide an interlocking trellis of laws which will enable government at all levels to more effectively control the [narcotic and dangerous drug] problem." Special Message to the Congress on Control of Narcotics and Dangerous Drugs, Pub. Papers of the Presidents of the United States: Richard Nixon, 1969, at 513, 514 (July 14, 1969).

The drafters of the Uniform Act identified a concern—similar to the issues the country faces again today—about the role that the diversion of pharmaceutical drugs played in the rise in drug abuse in the United States during the 1960s. At the time of the adoption of the Uniform Act and the federal Controlled Substance Act, "[o]ver 50 percent of the 'legally' manufactured

[11] McKesson erroneously claims that "[t]here is no obligation under Alabama law to report suspicious orders" notwithstanding this regulation. McKesson Br. at 13 (bold omitted). By the plain text of this regulation, a distributor is out of compliance with state law *either* if it fails to submit required reports to the DEA or to provide legible copies of those reports to the Alabama Board of Pharmacy. In other words, the regulation is violated if the state fails to receive a legible copy of a report that McKesson is required under federal law to submit to DEA, regardless if McKesson fails in the first instance to make the report to DEA or simply to provide a copy to the state. *See also* Alabama Br. at 34-35.

[12] Both the Uniform Act and the federal Controlled Substances Act have been amended since their original 1970 versions. *See, e.g.*, Uniform Controlled Substances Act (1994). However, the relevant provisions related to regulating the distribution of controlled substances have remained largely unchanged.

amphetamines in the United States [were being] diverted into illegal channels," and that "this extraordinarily high diversion rate ha[d] continued for at least 5 years" but that "[d]rug companies ha[d] not voluntarily curtailed production." 116 Cong. Rec. 35,551 (Oct. 7, 1970) (statement of Sen. Eagleton).

In an effort to address diversion in their model legislation for states, the drafters specifically identified a main objective of the Act: to establish a closed regulatory system for the legitimate handlers of controlled drugs in order better to prevent illicit drug diversion. Uniform Act, prefatory note. Specifically, the Act was designed to "close the gaps in State laws and thus eliminate many of these sources of diversion, both actual and potential." Uniform Act § 302 cmt. By incorporating the Uniform Act into state law, state legislators achieved their purpose in combating diversion by establishing a closed regulatory system within each state that prevented controlled substances going from legitimate channels to illegitimate channels. *Pharm. Mfrs. Ass'n v. N.M. Bd. of Pharm.*, 525 P.2d 931, 936 (N.M. Ct. App. 1974); *see also United States v. Moore*, 423 U.S. 122, 135 (1975) (observing that Congress intended the federal Controlled Substances Act to guard against diversion of abuse-prone prescription medications "from legitimate channels to illegitimate channels" because entities with access to medications moving through legitimate channels "were responsible for a large part of the illegal drug traffic").

By adopting the Uniform Act, the states have created closed systems to prevent the diversion of controlled substances and regulated the distributors of these substances.

C. States Properly Impose Duties to Prevent Diversion and Detect Suspicious Orders that Parallel Those of the Federal Controlled Substances Act.

McKesson argues that Alabama's claims fail because Alabama has no federal law right of action against distributors. McKesson is wrong because states may through their state laws impose duties similar to federal law. Pursuant to the scheme established by the Uniform Act,

they have done so with respect to opioid distributors' duties to prevent diversion and detect suspicious orders.

States may adopt federal requirements as their own laws and regulations unless a constitutionally valid provision of federal law preempts states from doing so. *See, e.g.*, *California v. Zook*, 336 U.S. 725, 735 (1949) (holding that a state statute was not preempted when "there is no conflict in terms, and no possibility of such conflict, for the state statute makes federal law its own in this particular"). And the state law provisions that adopt federal requirements may authorize the state (or its citizens) to sue to enforce noncompliance with those duties, again unless a constitutionally valid provision of federal law preempts states from doing so. *See, e.g., Air Conditioning & Refrigeration Inst. v. Energy Res. Conservation & Dev. Comm'n*, 410 F.3d 492, 502 (9th Cir. 2005) ("[I]f state law adopts or imposes a . . . requirement that is the same as the federal standard, even if the state law provides compensation or other remedies for a violation, so long as Congress chooses not to explicitly preempt the consistent law, it will not be said to be in conflict with federal law." (quoting *Worm v. Am. Cyanamid Co.*, 970 F.2d 1301, 1307 (4th Cir. 1992))).

The federal Controlled Substances Act neither preempts states from incorporating distributors' federal requirements into state law nor preempts states from making those requirements judicially enforceable. In fact, the federal Controlled Substances Act specifically disavows any interpretation that would preempt states from regulating in the same area "unless there is a positive conflict between that provision of this title and that State law so that the two cannot consistently stand together." 21 U.S.C. § 903. This point only bolsters the conclusion that the federal Controlled Substances Act is enforced in concert with state regimes of regulation and enforcement.

D. State Attorneys General Have Common-Law or Statutory Authority to Enforce State Controlled Substances Laws and to Seek Monetary Remedies Under Those Laws.

Perhaps anticipating that it will not be successful in denying the states' authority to prevent diversion and monitor suspicious orders, McKesson argues, alternatively, that the Court should dismiss Alabama's complaint because "nothing in the [Alabama] statute . . . authorizes the State to seek compensatory or consequential 'damages' on the basis of alleged violations of the Alabama CSA." McKesson Br. at 11-12. This argument is wrong, because state attorneys general have full authority to take civil action seeking monetary remedies—including damages for past harm, civil penalties, and future costs necessary to remediate harm—to enforce the duties imposed on distributors by state controlled substance laws.[13]

Most state attorneys general derive their power, at least in part, from the common law. *See State ex rel. Derryberry v. Kerr-Mcgee Corp.*, 516 P.2d 813, 818-19 (Okla. 1973) (citing law from numerous states). "Under the common law, the attorney general has the power to bring any action which he or she thinks necessary to protect the public interest, a broad grant of authority which includes the power to act to enforce the state's statutes." 7 Am. Jur. 2d *Attorney General* § 5. The California courts have also noted that "[t]he attorney-general, as the chief law officer of the state . . . in the absence of any legislative restriction, has the power to file any civil action . . . which he deems necessary for the enforcement of the laws of the state . . . ." *People ex rel. Harris v. Rizzo*, 154 Cal. Rptr. 3d 443, 458 (Cal. Ct. App. 2013). In those states where the Attorney General lacks inherent common-law powers, "the statutes in the various jurisdictions are, as a rule, more or less declaratory of the common law." 7 Am. Jur. 2d *Attorney General* § 5.

[13] With respect to at least some causes of action, other governmental and private parties may have the legal right to enforce these state-law duties. This issue, which may have varying answers in different states, is beyond the scope of this brief.

As Alabama explains, it can obtain monetary remedies for violation of distributors' anti-diversion and suspicious order reporting duties under the Uniform Act through its claims for nuisance, negligence, and wantonness. Alabama Br. at 37, 40-43. Moreover, as explained below, in addition to common-law authority, state consumer protection statutes—including Alabama's—provide specific authority to enforce distributors' anti-diversion and suspicious order reporting duties under the Uniform Act and to obtain monetary remedies for their violations.

II. McKesson's Remaining Scattershot Arguments Do Not Apply to Sovereign Enforcement of State Consumer Protection Laws or to State Common-Law Claims.

McKesson argues that Alabama is not eligible for relief because the free public services doctrine bars its claims, because it does not adequately plead proximate causation, and because its injuries are supposedly derived from harm to others. McKesson's arguments are largely based on principles that apply to private parties enforcing private rights of action in tort. But states, unlike private parties, have broad authority under consumer laws that prohibit unfair and/or deceptive business practices ("UDAP") and under common law to protect consumers and safeguard the integrity of state industries. Accordingly, states need not allege proximate cause when bringing enforcement actions under UDAP statutes. Likewise, states' consumer protection claims are not barred by the derivative injury rule or the free public services doctrine.

A. States Have Broad Authority to Protect Consumers Through *Parens Patriae* Authority and Under State UDAP Statutes.

States protect their consumers and the integrity of their marketplaces under their state UDAP statutes or as *parens patriae*. *See generally Mississippi ex rel. Hood v. AU Optronics Corp*, 571 U.S. 161 (2014); *AU Optronics Corp. v. South Carolina*, 699 F.3d 385 (4th Cir. 2012); *Nevada v. Bank of Am. Corp.*, 672 F.3d 661 (9th Cir. 2012). The Supreme Court has long recognized states' standing to bring suits based on sovereign interests. *See Alfred L. Snapp &*

Son, Inc., 458 U.S. at 607 (recognizing a state's interest in preventing and/or remedying harm to "the health and well-being—both physical and economic—of its residents in general").

In addition to states' standing as *parens patriae*, all fifty states have enacted UDAP laws that may be enforced by the sovereign. State attorneys general bring actions under these UDAP statutes to target deceptive business conduct. *See* Jonathan Sheldon et al., Nat'l Consumer Law Ctr., *Unfair and Deceptive Acts and Practices* §§ 1.1, 12.2.1, 13.1 (9th ed. 2016); Prentiss Cox et al. *Strategies of Public UDAP Enforcement*, 55 Harv. J. on Legis. 37 (2017). The sovereign enforcement provision of Alabama's Deceptive Trade Practices Act ("DTPA"), Ala. Code § 8-19-8, parallels the UDAP sovereign enforcement provisions in other states. Ala. Code §§ 8-19-8, 8-19-11.

McKesson disregards the special role state attorneys general play in protecting consumers by conflating private UDAP claims with sovereign UDAP enforcement. But courts have uniformly recognized that the purpose of sovereign enforcement actions is eliminating unfair or deceptive practices "to vindicate the public interest rather than to redress individual grievances" or to act as a proxy for individual citizens' private claims. *Mayton v. Hiatt's Used Cars, Inc.*, 262 S.E.2d 860, 863 (N.C. Ct. App. 1980). The court in *In re Standard & Poor's Rating Agency Litigation*, for example, expressly recognized the distinctions between private and sovereign UDAP actions and highlighted the objective of states in enforcing UDAP statutes to eliminate unfair and deceptive business practices from the marketplace. *In re Std. & Poor's Rating Agency Litig.*, 23 F. Supp. 3d 378, 407 (S.D.N.Y. 2014).

B. The Free Public Services Doctrine Does Not Bar State Claims.

The "free public services" doctrine does not bar recovery under Alabama's common-law claims to recover its expenditures related to the opioid epidemic. Nor does the doctrine preclude states from enforcing UDAP statutes.

The free public services doctrine is potentially applicable when a government entity seeks recovery for unremarkable emergency services whose costs are commonly levied on the public. Courts have found that the rule typically applies in those cases in which a single negligent event or act causes increased costs to governmental entities as they respond to one-off crises. *See, e.g.*, *City of Flagstaff v. Atchison, Topeka & Santa Fe Ry. Co.*, 719 F.2d 322, 323 (9th Cir. 1983) (government costs incurred in evacuating residents after a train derailment).[14]

The costs incurred by Alabama, the Amici States, and every state nationwide to address the opioid crisis are substantial, wide-ranging, and ongoing. *See* Compl. ¶¶ 355-66. The conduct alleged in this case and the costs incurred render the doctrine inapplicable in this context.

Where, as here, a tortfeasor's continued misconduct causes a state to expend a significant amount of resources to mitigate the consequences of the misconduct, the state may recoup those costs. *See, e.g.*, *James v. Arms Tech., Inc*., 820 A.2d 27, 48-49 (N.J. Super. Ct. App. Div. 2003) (refusing to apply the free public services doctrine where the plaintiff claimed a repeated course of conduct by gun manufacturers, distributors, and retailers that required the government to expend substantial sums on a continual basis).

Here, the costs that Alabama and other states are seeking to recover are not associated with run-of-the-mill emergency services within the ambit of the free public services doctrine.[15] As Alabama's complaint alleges, the opioid epidemic has increased governmental costs

[14] The brief addresses only McKesson's claim that the free public services doctrine applies to the State of Alabama's causes of action, McKesson Br. at 10-11, and not the separate "municipal cost recovery rule" that is inapplicable to states.

[15] Additionally, many of the monetary remedies that states are seeking are civil penalties and future costs necessary to remediate harm, and not the recovery of past costs. States, like Alabama, are uniquely situated in being authorized to pursue recoveries in this matter under their UDAP statutes and the Uniform Act.

nationwide, in areas ranging from healthcare treatment costs to losses of productivity and tax revenue. *See* Compl. ¶¶ 360-63. In fact, a recent estimate by the Council of Economic Advisers places the true cost of the opioid epidemic at $504.0 billion nationwide for the year 2015 alone. *See* Council of Economic Advisors, *The Underestimated Cost of the Opioid Crisis* 1 (2017). The free public services doctrine should not apply to bar the recovery of states' costs related to McKesson's continuous, intentional, and deceptive conduct.

Moreover, courts have routinely found that the free public services doctrine does not apply where recovery is authorized by statute or regulation or where a state is seeking to recover the costs of public services expended to abate a nuisance. *See* Alabama Br. at 8-9. Alabama alleges that the opioid epidemic is a public nuisance that was fueled, in part, by McKesson's actions, and these actions continue to threaten the health, safety, and welfare of Alabamans. The damages that Alabama seeks relate directly to the abatement of the public nuisance it alleges McKesson caused. Accordingly, the free public services doctrine does not apply to Alabama's common law claims.[16]

The Court should also reject McKesson's application of the free public services doctrine to sovereign enforcement of UDAP statutes. The doctrine does not diminish states' authority under UDAP statutes to bring consumer protection enforcement actions. *Koch v. Consol. Edison Co. of N.Y., Inc.*, 468 N.E.2d 1, 8 (N.Y. 1984).

[16] Alabama alleges that recovery from McKesson will directly abate the nuisance. *See* Compl. ¶¶ 369, 375, 378-79. As a result, the Illinois Supreme Court's use of the free public services doctrine to preclude a governmental plaintiff from recovering damages against a gun manufacturer is inapposite. *See City of Chicago v. Beretta U.S.A. Corp.*, 821 N.E.2d 1099 (Ill. 2004). In that case, the Illinois Supreme Court expressly held that the reason it applied the free public services doctrine was that the governmental plaintiff admitted that recovery would not abate the nuisance. *Id*. at 1147.

None of the cases on which McKesson relies applies the doctrine to bar sovereign enforcement of a UDAP statute. On the contrary, in the one reported case in which a defendant challenged a UDAP statute claim based on the free public services doctrine, the court summarily rejected the challenge. *See State v. Lead Ind. Ass'n, Inc.*, No. 99-5226, 2001 WL 345830, at *5 (R.I. Super. Ct. Apr. 2, 2001). Accordingly, the free public services doctrine does not bar a claim under a UDAP statute by a sovereign.

C. Sovereign Enforcement Actions Under UDAP Statutes Do Not Require a Showing of Proximate Cause.

McKesson conflates the requirements for private and sovereign UDAP actions by arguing that Alabama did not adequately allege that its injuries were proximately caused by McKesson's deceptive conduct. McKesson's efforts to impose requirements for private plaintiffs under the DTPA on Alabama's sovereign enforcement claim should be rejected.

Inherent in the distinction between private and sovereign actions is the more relaxed showing that sovereigns must make to state a claim under UDAP statutes. Private actions and sovereign actions under state UDAP statutes involve different elements. Courts have routinely found, for example, that sovereigns need not prove reliance or proximate causation to obtain relief under state UDAP statutes. *See, e.g., Weinberg v. Sun Co.*, 777 A.2d 442, 445 (Pa. 2001) (under Pennsylvania's UDAP statute, private plaintiffs must show reliance and causation, but the State need only prove that a practice is unlawful and that proceedings would be in the public interest); *Elipas Enters. v. Silverstein*, 612 N.E.2d 9, 12 (Ill. App. Ct. 1993) (private consumers could not prevail on claims under Illinois' UDAP statute without establishing reasonable reliance on deceptive conduct, but the State need not establish reasonable reliance); *Thiedemann v. Mercedes-Benz USA, LLC*, 872 A.2d 783, 790-92 (N.J. 2005) (recognizing that private plaintiffs

must plead an "[ascertainable] loss attributable to conduct made unlawful by the [Consumer Fraud Act]" but Attorney General need not).

None of the cases that McKesson relies on contradicts this tenet of UDAP enforcement. This is because none of the cases McKesson cites involved sovereign enforcement of state UDAP claims. This Court should reject McKesson's claim that failure to allege proximate causation is fatal to a state's UDAP claims.

D. The Derivative Injury Rule Does Not Apply to Sovereign Actions Under UDAP Statutes.

McKesson also incorrectly claims that the "derivative injury rule" applies to sovereign UDAP claims. But the derivative injury rule is inapplicable in sovereign actions under UDAP statutes.

The derivative injury rule tests whether a party has standing to sue. When putative harm suffered by a private plaintiff is entirely derivative of harm to others, the harm may be "too remote" to support standing. *See, e.g.*, *Laborers Local 17 Health & Benefit Fund v. Philip Morris, Inc.*, 191 F.3d 229, 236-38 (2d Cir. 1999).

But a state's standing under a UDAP statute is not based on individual injuries at all. Instead, a state's standing is based on explicit enforcement authority conferred by the UDAP statute. State UDAP statutes authorize states to seek injunctive and equitable relief—in the states' own names—to eliminate unfair and deceptive business practices. *In re Std. & Poor's Rating Agency Litig*., 23 F. Supp. 3d at 406; *AU Optronics Corp*., 699 F.3d at 394.

Tellingly, neither of the cases upon which McKesson relies applies the derivative injury rule to a sovereign UDAP claim. *See* McKesson Br. at 7. In *State ex rel. Miller v. Philip Morris Inc.*, the court applied the derivative injury rule to Iowa's common law claims but not to Iowa's UDAP claims. *State ex rel. Miller v. Philip Morris Inc.*, 577 N.W.2d 401 (Iowa 1998).

Similarly, in *Maryland v. Philip Morris, Inc.*, the court applied the derivative injury rule to Maryland's common law claims but not to its UDAP or antitrust claims. *Maryland v. Philip Morris, Inc.*, No. 96122017, 1997 WL 540913 (Md. Cir. Ct. May 21, 1997). This Court should reject McKesson's application of the derivative injury rule to state UDAP claims.

CONCLUSION

The Court should deny McKesson's motion to dismiss Alabama's first amended complaint.

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CERTIFICATE OF SERVICE

I hereby certify that on August 10, 2018 the foregoing was filed electronically. Notice of this filing will be sent by operation of the Court's electronic filing system to all parties indicated on the electronic filing receipt. Parties may access this filing through the Court's system.

/s/ *Steve W. Berman*
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Exhibit A

NORTH CAROLINA
SUPREME COURT LIBRARY
RALEIGH

HANDBOOK

OF THE

NATIONAL CONFERENCE OF COMMISSIONERS

ON

UNIFORM STATE LAWS

AND

PROCEEDINGS

OF THE

ANNUAL CONFERENCE MEETING IN ITS SEVENTY-NINTH YEAR

CLAYTON, MISSOURI
AUGUST 1-7
1970

HEADQUARTERS OFFICE
1155 East 60th Street
Chicago, Illinois 60637

UNIFORM CONTROLLED SUBSTANCES ACT

Prefatory Note

The Uniform Controlled Substances Act is designed to supplant the Uniform Narcotic Drug Act, adopted by the National Conference of Commissioners on Uniform State Laws in 1933, and the Model State Drug Abuse Control Act, relating to depressant, stimulant, and hallucinogenic drugs, promulgated in 1966. With the enactment of the new Federal narcotic and dangerous drug law, the "Comprehensive Drug Abuse Prevention and Control Act of 1970" (Public Law 91-513, short title "Controlled Substances Act"), it is necessary that the States update and revise their narcotic, marihuana, and dangerous drug laws.

This Uniform Act was drafted to achieve uniformity between the laws of the several States and those of the Federal government. It has been designed to complement the new Federal narcotic and dangerous drug legislation and provide an interlocking trellis of Federal and State law to enable government at all levels to control more effectively the drug abuse problem.

The exploding drug abuse problem in the past ten years has reached epidemic proportions. No longer is the problem confined to a few major cities or to a particular economic group. Today it encompasses almost every nationality, race, and economic level. It has moved from the major urban areas into the suburban and even rural communities, and has manifested itself in every State in the Union.

Much of this major increase in drug use and abuse is attributable to the increased mobility of our citizens and their affluence. As modern American society becomes increasingly mobile, drugs clandestinely manufactured or illegally diverted from legitimate channels in one part of a State are easily transported for sale to another part of that State or even to another State. Nowhere is this mobility manifested with greater impact than in the legitimate pharmaceutical industry. The lines of distribution of the products of this major national industry cross in and out of a State innumerable times during the manufacturing or distribution processes. To assure the continued free movement of controlled substances between States, while at the same time securing such States against drug diversion from legitimate sources, it becomes critical to approach not only the control of illicit and

legitimate traffic in these substances at the national and international levels, but also to approach this problem at the State and local level on a uniform basis.

A main objective of this Uniform Act is to create a coordinated and codified system of drug control, similar to that utilized at the Federal level, which classifies all narcotics, marihuana, and dangerous drugs subject to control into five schedules, with each schedule having its own criteria for drug placement. This classification system will enable the agency charged with implementing it to add, delete, or reschedule substances based upon new scientific findings and the abuse potential of the substance.

Another objective of this Act is to establish a closed regulatory system for the legitimate handlers of controlled drugs in order better to prevent illicit drug diversion. This system will require that these individuals register with a designated State agency, maintain records, and make biennial inventories of all controlled drug stocks.

The Act sets out the prohibited activities in detail, but does not prescribe specific fines or sentences, this being left to the discretion of the individual States. It further provides innovative law enforcement tools to improve investigative efforts and provides for interim education and training programs relating to the drug abuse problem.

The Uniform Act updates and improves existing State laws and insures legislative and administrative flexibility to enable the States to cope with both present and future drug problems. It is recognized that law enforcement may not be the ultimate solution to the drug abuse problem. It is hoped that present research efforts will be continued and vigorously expanded, particularly as they relate to the development of rehabilitation, treatment, and educational programs for addicts, drug dependent persons, and potential drug abusers.

UNIFORM CONTROLLED SUBSTANCES ACT

ARTICLE I

[DEFINITIONS]

SECTION 101. [*Definitions.*] As used in this Act:

(a) "Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by:

(1) a practitioner (or, in his presence, by his authorized agent), or

(2) the patient or research subject at the direction and in the presence of the practitioner.

(b) "Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser. It does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman.

(c) "Bureau" means the Bureau of Narcotics and Dangerous Drugs, United States Department of Justice, or its successor agency.

(d) "Controlled substance" means a drug, substance, or immediate precursor in Schedules I through V of Article II.

(e) "Counterfeit substance" means a controlled substance which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, number or device, or any likeness thereof, of a manufacturer, distributor, or dispenser other than the person who in fact manufactured, distributed, or dispensed the substance.

(f) "Deliver" or "delivery" means the actual, constructive, or attempted transfer from one person to another of a controlled substance, whether or not there is an agency relationship.

(g) "Dispense" means to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery.

(h) "Dispenser" means a practitioner who dispenses.

(i) "Distribute" means to deliver other than by administering or dispensing a controlled substance.

(j) "Distributor" means a person who distributes.

(k) "Drug" means (1) substances recognized as drugs in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; (2) substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals; (3) substances (other than food) intended to affect the structure or any function of the body of man or animals; and (4) substances intended for use as a component of any article specified in clause (1), (2), or (3) of this subsection. It does not include devices or their components, parts, or accessories.

(l) "Immediate precursor" means a substance which the [appropriate person or agency] has found to be and by rule designates as being the principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail, or limit manufacture.

(m) "Manufacture" means the production, preparation, propagation, compounding, conversion or processing of a controlled substance, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container, except that this term does not include the preparation or compounding of a controlled substance by an individual for his own use or the preparation, compounding, packaging, or labeling of a controlled substance:

(1) by a practitioner as an incident to his administering or dispensing of a controlled substance in the course of his professional practice, or

(2) by a practitioner, or by his authorized agent under his supervision, for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale.

(n) "Marihuana" means all parts of the plant *Cannabis sativa L.*, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin. It does not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture,

salt, derivative, mixture, or preparation of the mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of the plant which is incapable of germination

(o) "Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate.

(2) Any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause 1, but not including the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) Coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extractions of coca leaves which do not contain cocaine or ecgonine.

(p) "Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability. It does not include, unless specifically designated as controlled under Section 201 of this Act, the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms.

(q) "Opium poppy" means the plant of the species *Papaver somniferum L.*, except its seeds.

(r) "Person" means individual, corporation, government or governmental subdivision or agency, business trust, estate, trust, partnership or association, or any other legal entity.

(s) "Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

(t) "Practitioner" means:

(1) A physician, dentist, veterinarian, scientific investigator, or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in this State.

(2) A pharmacy, hospital or other institution licensed, registered, or otherwise permitted to distribute, dispense, conduct

research with respect to or to administer a controlled substance in the course of professional practice or research in this State.

(u) "Production" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance.

(v) "State," when applied to a part of the United States, includes any state, district, commonwealth, territory, insular possession thereof, and any area subject to the legal authority of the United States of America.

(w) "Ultimate user" means a person who lawfully possesses a controlled substance for his own use or for the use of a member of his household or for administering to an animal owned by him or by a member of his household.

ARTICLE II

[STANDARDS AND SCHEDULES]

SECTION 201. [*Authority to Control.*]

(a) The [appropriate person or agency] shall administer this Act and may add substances to or delete or reschedule all substances enumerated in the schedules in sections 204, 206, 208, 210, or 212 pursuant to the procedures of [insert appropriate State administrative procedures code section]. In making a determination regarding a substance, the [appropriate person or agency] shall consider the following:

(1) the actual or relative potential for abuse;

(2) the scientific evidence of its pharmacological effect, if known;

(3) the state of current scientific knowledge regarding the substance;

(4) the history and current pattern of abuse;

(5) the scope, duration, and significance of abuse;

(6) the risk to the public health;

(7) the potential of the substance to produce psychic or physiological dependence liability; and

(8) whether the substance is an immediate precursor of a substance already controlled under this Article.

(b) After considering the factors enumerated in subsection (a) the [appropriate person or agency] shall make findings with respect thereto and issue a rule controlling the substance if he [it] finds the substance has a potential for abuse.

(c) If the [appropriate person or agency] designates a substance as an immediate precursor, substances which are precursors of the controlled precursors shall not be subject to control solely because they are precursors of the controlled precursor.

(d) If any substance is designated, rescheduled, or deleted as a controlled substance under Federal law and notice thereof is given to the [appropriate person or agency], the [appropriate person or agency] shall similarly control the substance under this Act after the expiration of 30 days from publication in the Federal Register of a final order designating a substance as a controlled substance or rescheduling or deleting a substance, unless within that 30 day period, the [appropriate person or agency] objects to inclusion, rescheduling, or deletion. In that case, the [appropriate person or agency] shall publish the reasons for objection and afford all interested parties an opportunity to be heard. At the conclusion of the hearing, the [appropriate person or agency] shall publish his [its] decision, which shall be final unless altered by statute. Upon publication of objection to inclusion, rescheduling, or deletion under this Act by the [appropriate person or agency], control under this Act is stayed until the [appropriate person or agency] publishes his [its] decision.

(e) Authority to control under this section does not extend to distilled spirits, wine, malt beverages, or tobacco as those terms are defined or used in [insert relevant sections if applicable].

COMMENT

The Act vests the authority to administer its provisions in the appropriate person or agency within the State. The "appropriate" person or agency may be one or more persons, or one or more agencies, or a combination. The enacting State should designate that person or agency which has the means to implement, enforce, and regulate the provisions of the Act. For example, authority could be vested in the Office of the Attorney General, a Department of Health, a Division of Public Safety, or such other agency within the State responsible for regulating and enforcing the drug laws. An alternative might be a division of authority whereby one agency might be responsible for controlling drugs under this Article, another agency might be designated to regulate the legitimate industry under Article III, and still another agency might be charged with enforcement. In any event, the ultimate authority for determining the appropriate person or agency is vested in the enacting State.

Section 201 sets out the criteria to be considered for the control and classification of drugs into the several schedules. These criteria consist of the degree of their abuse potential, known effect, harmfulness and level of accepted medical use. All controlled substances are contained in either Schedule I, II, III, IV or V. This classification achieves one of the main objectives of the Uniform Act, which is to create a coordinated, codified system of drug control and regulation.

The Act recognizes that some States have had more stringent laws relating to substances than did the former Federal laws. The Uniform Act follows the Federal Controlled Substances Act and lists all of the controlled substances in five schedules which are identical with the Federal law. The Uniform Act is not intended to prevent a State from adding or removing substances from the

schedules, or from reclassifying substances from one schedule to another, provided the procedures specified in Section 201 are followed.

To bring a substance under control through the administrative procedures, the designated State authority will make findings with respect to the eight criteria, hereinafter enumerated, and issue an order controlling the given substance if it has a potential for abuse. To avoid potential State Constitutional problems, as well as allegations of improper legislative delegation of authority, a procedure has been set out which will require substances controlled by Federal laws to be controlled under the State law after the designated authority is notified and after the expiration of thirty days from the date of publication in the Federal Register of a final order controlling the substance under Federal law. However, the designated authority in the State may object to inclusion of the substance under this Act. It must give public notice of its objections and afford an opportunity for any interested party to be heard on the matter. The designated authority makes a final decision based upon that hearing, which is considered final unless specifically acted upon in a contrary manner by the legislature. If the designated authority publicly objects to inclusion of a substance under the controls of this Act, control is automatically stayed pending the outcome of the hearing and the designated authority's final decision. Once a final decision is rendered controlling the substance, the stay automatically terminates and the substance is deemed controlled under this Act.

The eight criteria to be considered with regard to a substance are as follows:

(1) *Its actual or relative potential for abuse*—

These are the criteria which will be used most often to control drugs and will provide the basis for the greatest controversy. The term "potential for abuse" is found in the definition of a "depressant or stimulant drug" in the Drug Control Amendments of 1965 (21 U.S.C. 201(v)) and is characterized further in the regulations (21 CFR 166.2(e)) promulgated under those regulations as follows:

"The Director of the Bureau of Narcotics and Dangerous Drugs may determine that a substance has a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect if:

(1) There is evidence that individuals are taking the drug or drugs containing such a substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or of the community; or

(2) There is significant diversion of the drug or drugs containing such a substance from legitimate drug channels; or

(3) Individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice; or

(4) The drug or drugs containing such a substance are new drugs so related in their action to a drug or drugs already listed as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community."

These regulations follow and extend the suggestions contained in House Report No. 130, 89th Congress, First Session, page 7 (1965).

The report went further in its discussion of the "potential" aspect of the term. It stated that it did not intend that potential for abuse be determined on the basis of "isolated or occasional non-therapeutic purposes." The House Interstate and Foreign Commerce Committee felt that there must exist "a substantial

potential for the occurrence of significant diversions from legitimate channels, significant use by individuals contrary to professional advice, or substantial capability of creating hazards to the health of the user or the safety of the community." (at page 7)

There are two points that should be emphasized in this definition. First, the House Committee was speaking of *"potential"* rather than *"actual"* abuse. In considering a drug for control, it would not be necessary to show that abuse presently exists but only that there are indications of a potential for abuse. This is borne out by the Committee's statement that "the Secreary of Health, Education, and Welfare should not be required to wait until a number of lives have been destroyed or substantial problems have already arisen before designating a drug as subject to controls of the bill." (at page 7). Thus, the incidence of present abuse is not the test which must be applied. The test is a determination of future or potential abuse. The second point of emphasis is that in speaking of "substantial" potential the term "substantial" means more than a mere scintilla of isolated abuse, but less than a preponderance. Therefore, documentation that, say, several hundred thousand dosage units of a drug have been diverted would be "substantial" evidence of abuse despite the fact that tens of millions of dosage units of that drug are legitimately used in the same time period. The normal way in which such diversion is shown is by accountability audits of the legitimate sources of distribution, such as manufacturers, wholesalers, pharmacies and doctors.

Misuse of a drug in suicides and attempted suicides, as well as injuries resulting from unsupervised use also would be regarded as indicative of a drug's potential for abuse.

(2) *Scientific evidence of its pharmacological effects*—

The state of knowledge with respect to the uses of a specific drug are, of course, major considerations, e.g., it is vital to know whether or not a drug has an hallucinogenic effect if it is to be controlled because of that effect.

(3) *The statement of current scientific knowledge regarding the substance*—

Criteria (2) and (3) are closely related. However, (2) is primarily interested in pharmacological effects and (3) deals with all scientific knowledge with respect to the substance.

(4) *Its history and current pattern of abuse*—

To determine whether or not a drug should be controlled, the designated State authority must know the pattern of abuse of that substance, including the social, economic and ecological characteristics of the segments of the population involved in such abuse.

(5) *The scope, duration, and significance of abuse*—

Not only must the designated State authority know the pattern of abuse, but it must know whether the abuse is widespread. It must also know whether it is a passing fad, like smoking banana peels, or whether it is a significant chronic abuse problem like heroin addiction. In reaching this decision, the State authority should consider the economics of regulation and enforcement attendant to such a decision. In addition, it should be aware of the social significance and impact of such a decision upon those people, especially the young, that would be affected by it.

(6) *What, if any, risk there is to the public health*—

The designated State authority must have the best available knowledge of the pharmacological properties of any drug under consideration. If a drug creates no danger to the public health, it would be inappropriate to control the drug under this Act.

(7) *Its psychic or physiological dependence liability*—

There must be an assessment of the extent to which a drug is physically addictive or psychologically habit forming, if such information is known.

(8) *Whether the substance is an immediate precursor of a substance already controlled*—

This criterion allows inclusion of immediate precursors on this basis alone into the appropriate schedule and thus safeguards against possibilities of clandestine manufacture.

The overall intent of this Section is to create reasonable flexibility within the Uniform Act so that, as new substances are discovered or found to have an abuse potential, they can speedily be brought under control without constant resort to the legislature. Such flexibility will allow the laws to keep in step with new trends in drug abuse and new scientific information. States should consider establishing a Scientific Advisory Committee consisting of leading medical and pharmaceutical professionals to advise the appropriate person or agency on control of substances.

SECTION 202. [*Nomenclature.*] The controlled substances listed or to be listed in the schedules in sections 204, 206, 208, 210, and 212 are included by whatever official, common, usual, chemical, or trade name designated.

SECTION 203. [*Schedule I Tests.*] The [appropriate person or agency] shall place a substance in Schedule I if he [it] finds that the substance:

(1) has high potential for abuse; and

(2) has no accepted medical use in treatment in the United States or lacks accepted safety for use in treatment under medical supervision.

COMMENT

Based upon these criteria, hallucinogenic substances and certain narcotic substances are included in the same schedule (Section 204). This is primarily because both groups of drugs have no accepted use in the United States and both have a high potential for abuse. However, hallucinogenic substances in Schedule I are not treated in the same manner for penalty purposes as narcotic substances. (See Prohibited Acts A, Section 401.)

Experimental substances found to have a potential for abuse in early testing will also be included in Schedule I. When those substances are accepted by the Federal Food and Drug Administration as being safe and effective, they will then be considered to have an accepted medical use for treatment in the United States, and thus, will be eligible to be shifted to an appropriate schedule based upon the criteria set out in Sections 205, 207, 209, and 211.

SECTION 204. [*Schedule I.*] (a) The controlled substances listed in this section are included in Schedule I.

(b) Any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters,

ethers and salts is possible within the specific chemical designation:

(1) Acetylmethadol;
(2) Allylprodine;
(3) Alphacetylmethadol;
(4) Alphameprodine;
(5) Alphamethadol;
(6) Benzethidine;
(7) Betacetylmethadol;
(8) Betameprodine;
(9) Betamethadol;
(10) Betaprodine;
(11) Clonitazene;
(12) Dextromoramide;
(13) Dextrorphan;
(14) Diampromide;
(15) Diethylthiambutene;
(16) Dimenoxadol;
(17) Dimepheptanol;
(18) Dimethylthiambutene;
(19) Dioxaphetyl butyrate;
(20) Dipipanone;
(21) Ethylmethylthiambutene;
(22) Etonitazene;
(23) Etoxeridine;
(24) Furethidine;
(25) Hydroxypethidine;
(26) Ketobemidone;
(27) Levomoramide;
(28) Levophenacylmorphan;
(29) Morpheridine;
(30) Noracymethadol;
(31) Norlevorphanol;
(32) Normethadone;
(33) Norpipanone;
(34) Phenadoxone;
(35) Phenampromide;
(36) Phenomorphan;
(37) Phenoperidine;
(38) Piritramide;
(39) Proheptazine;
(40) Properidine;
(41) Racemoramide;
(42) Trimeperidine.

(c) Any of the following opium derivatives, their salts, isomers and salts of isomers, unless specifically excepted, whenever the existence of these salts, isomers and salts of isomers is possible within the specific chemical designation:

(1) Acetorphine;
(2) Acetyldihydrocodeine;
(3) Benzylmorphine;
(4) Codeine methylbromide;
(5) Codeine-N-Oxide;
(6) Cyprenorphine;
(7) Desomorphine;
(8) Dihydromorphine;
(9) Etorphine;
(10) Heroin;
(11) Hydromorphinol;
(12) Methyldesorphine;
(13) Methyldihydromorphine;
(14) Morphine methylbromide;
(15) Morphine methylsulfonate;
(16) Morphine-N-Oxide;
(17) Myrophine;
(18) Nicocodeine;
(19) Nicomorphine;
(20) Normorphine;
(21) Phoclodine;
(22) Thebacon.

(d) Any material, compound, mixture or preparation which contains any quantity of the following hallucinogenic substances, their salts, isomers and salts of isomers, unless specifically excepted, whenever the existence of these salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) 3,4-methylenedioxy amphetamine;
(2) 5-methoxy-3,4-methylenedioxy amphetamine;
(3) 3,4,5-trimethoxy amphetamine;
(4) Bufotenine;
(5) Diethyltryptamine;
(6) Dimethyltryptamine;
(7) 4-methyl-2, 5-dimethoxylamphetamine;
(8) Ibogaine;
(9) Lysergic acid diethylamide;
(10) Marihuana;
(11) Mescaline;
(12) Peyote;

(13) N-ethyl-3-piperidyl benzilate;
(14) N-methyl-3-piperidyl benzilate;
(15) Psilocybin;
(16) Psilocyn;
(17) Tetrahydrocannabinols.

SECTION 205. [*Schedule II Tests.*] The [appropriate person or agency] shall place a substance in Schedule II if he [it] finds that:

(1) the substance has high potential for abuse;

(2) the substance has currently accepted medical use in treatment in the United States, or currently accepted medical use with severe restrictions; and

(3) the abuse of the substance may lead to severe psychic or physical dependence.

SECTION 206. [*Schedule II.*] (a) The controlled substances listed in this section are included in Schedule II.

(b) Any of the following substances, except those narcotic drugs listed in other schedules, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate.

(2) Any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in paragraph (1), but not including the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) Coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extractions which do not contain cocaine or ecgonine.

(c) Any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation:

(1) Alphaprodine;
(2) Anileridine;
(3) Bezitramide;
(4) Dihydrocodeine;
(5) Diphenoxylate;

(6) Fentanyl;
(7) Isomethadone;
(8) Levomethorphan;
(9) Levorphanol;
(10) Metazocine;
(11) Methadone;
(12) Methadone—Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane;
(13) Moramide—Intermediate, 2-methyl-3-morpholino-1, 1-diphenyl-propane-carboxylic acid;
(14) Pethidine;
(15) Pethidine—Intermediate—A, 4-cyano-1-methyl-4-phenylpiperidine;
(16) Pethidine—Intermediate—B, ethyl-4-phenylpiperidine-4-carboxylate;
(17) Pethidine—Intermediate—C, 1-methyl-4-phenylpiperidine-4-carboxylic acid;
(18) Phenazocine;
(19) Piminodine;
(20) Racemethorphan;
(21) Racemorphan.

COMMENT

Schedule II now includes only those substances principally considered as Class "A" narcotic drugs, i.e., narcotics dispensed only upon written prescription. It is contemplated that if stringent control of a nonnarcotic substance is required, the substance could be administratively added to Schedule II based upon the criteria set out in Section 205.

SECTION 207. [*Schedule III Tests.*] The [appropriate person or agency] shall place a substance in Schedule III if he [it] finds that:

(1) the substance has a potential for abuse less than the substances listed in Schedules I and II;
(2) The substance has currently accepted medical use in treatment in the United States; and
(3) abuse of the substance may lead to moderate or low physical dependence or high psychological dependence.

SECTION 208. [*Schedule III.*] (a) The controlled substances listed in this section are included in Schedule III.

(b) Any material, compound, mixture, or preparation which contains any quantity of the following substances having a potential for abuse associated with a stimulant effect on the central nervous system:

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers;

(2) Phenmetrazine and its salts;
(3) Any substance which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers;
(4) Methylphenidate.

(c) Unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a potential for abuse associated with a depressant effect on the central nervous system:

(1) Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid, except those substances which are specifically listed in other Schedules;
(2) Chlorhexadol;
(3) Glutethimide.
(4) Lysergic acid;
(5) Lysergic acid amide;
(6) Methyprylon;
(7) Phencyclidine;
(8) Sulfondiethylmethane;
(9) Sulfonethylmethane;
(10) Sulfonmethane.

(d) Nalorphine.

(e) Any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof:

(1) Not more than 1.8 grams of codeine, or any of its salts, per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium;
(2) Not more than 1.8 grams of codeine, or any of its salts, per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;
(3) Not more than 300 milligrams of dihydrocodeinone, or any of its salts, per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium;
(4) Not more than 300 milligrams of dihydrocodeinone, or any of its salts, per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;
(5) Not more than 1.8 grams of dihydrocodeine, or any of its salts, per 100 milliliters or not more than 90 milligrams

per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(6) Not more than 300 milligrams of ethylmorphine, or any of its salts, per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more ingredients in recognized therapeutic amounts;

(7) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(8) Not more than 50 milligrams of morphine, or any of its salts, per 100 milliliters or per 100 grams with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(f) The [appropriate person or agency] may except by rule any compound, mixture, or preparation containing any stimulant or depressant substance listed in subsections (b) and (c) from the application of all or any part of this Act if the compound, mixture, or preparation contains one or more active medicinal ingredients not having a stimulant or depressant effect on the central nervous system, and if the admixtures are included therein in combinations, quantity, proportion, or concentration that vitiate the potential for abuse of the substances which have a stimulant or depressant effect on the central nervous system.

COMMENT

Schedule III includes two categories of drugs—those narcotic drugs formerly considered Class "B" narcotics, and stimulant and depressant drugs formerly included under both the Model State Drug Abuse Control Act and the Federal Drug Abuse Control Amendments of 1965.

Subsection (e), which includes the former Class "B" narcotic drugs, reflects two changes. First, all calculations have been shifted from the historic apothecary system of measurement to the metric system to bring them in line with the general movement by many scientific groups and industries, including the pharmaceutical industry, to the metric system. Second, all dosage-strength calculations have been adjusted to correspond to the more modern 5 cc. teaspoon as a unit dose rather than the historic 3.69 cc. teaspoon size, upon which all previous calculations were made.

SECTION 209. [*Schedule IV Tests.*] The [appropriate person or agency] shall place a substance in Schedule IV if he [it] finds that:

(1) the substance has a low potential for abuse relative to substances in Schedule III;

(2) the substance has currently accepted medical use in treatment in the United States; and

(3) abuse of the substance may lead to limited physical dependence or psychological dependence relative to the substances in Schedule III.

SECTION 210. [*Schedule IV.*] (a) The controlled substances listed in this section are included in Schedule IV.

(b) Any material, compound, mixture, or preparation which contains any quantity of the following substances having a potential for abuse associated with a depressant effect on the central nervous system:

(1) Barbital;
(2) Chloral betaine;
(3) Chloral hydrate;
(4) Ethchlorvynol;
(5) Ethinamate;
(6) Methohexital;
(7) Meprobamate;
(8) Methylphenobarbital;
(9) Paraldehyde;
(10) Petrichloral;
(11) Phenobarbital.

(c) The [appropriate person or agency] may except by rule any compound, mixture, or preparation containing any depressant substance listed in subsection (b) from the application of all or any part of this Act if the compound, mixture, or preparation contains one or more active medicinal ingredients not having a depressant effect on the central nervous system, and if the admixtures are included therein in combinations, quantity, proportion, or concentration that vitiate the potential for abuse of the substances which have a depressant effect on the central nervous system.

COMMENT

Schedule IV contains certain tranquilizing drugs and long-acting barbiturates. All substances contained in the schedule must be dispensed on prescription.

SECTION 211. [*Schedule V Tests.*] The [appropriate person or agency] shall place a substance in Schedule V if he [it] finds that:

(1) the substance has low potential for abuse relative to the controlled substances listed in Schedule IV;

(2) the substance has currently accepted medical use in treatment in the United States; and

(3) the substance has limited physical dependence or psychological dependence liability relative to the controlled substances listed in Schedule IV.

SECTION 212. [*Schedule V.*]

(a) The controlled substances listed in this section are included in Schedule V.

(b) Any compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, which also contains one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation, valuable medicinal qualities other than those possessed by the narcotic drug alone:

(1) Not more than 200 milligrams of codeine, or any of its salts, per 100 milliliters or per 100 grams;

(2) Not more than 100 milligrams of dihydrocodeine, or any of its salts, per 100 milliliters or per 100 grams;

(3) Not more than 100 milligrams of ethylmorphine, or any of its salts, per 100 milliliters or per 100 grams;

(4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit;

(5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.

COMMENT

While it is contemplated that Schedule V drugs will be sold on a restricted over-the-counter sale basis for a valid medical purpose, this Section is not intended to supersede prescription requirements in those States where such substances cannot be sold except on a prescription-only status.

While this Schedule only contains narcotic drugs formerly considered as Class "X" (exempt over-the-counter drugs), the criteria set out in Section 211 are broad enough to include other over-the-counter preparations which meet those criteria and are in need of some limited form of control.

The comments to Section 208(e) relating to the metric system and the dosage-strength calculations apply equally as well to Schedule V.

SECTION 213. [*Republishing of Schedules.*] The [appropriate person or agency] shall revise and republish the schedules semi-annually for 2 years from the effective date of this Act, and thereafter annually.

ARTICLE III

[REGULATION OF MANUFACTURE, DISTRIBUTION AND DISPENSING OF CONTROLLED SUBSTANCES]

SECTION 301. [*Rules.*] The [appropriate person or agency] may promulgate rules and charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances within this State.

COMMENT

This Section will permit a State to cover the costs of actual registration and control by charging reasonable fees. However, the Section does not permit a State to charge exorbitant fees as a means of fully implementing the regulatory provisions of the Act and thereby avoiding the need for additional State appropriations.

SECTION 302. [*Registration Requirements.*]

(a) Every person who manufactures, distributes, or dispenses any controlled substance within this State or who proposes to engage in the manufacture, distribution, or dispensing of any controlled substance within this State, must obtain annually a registration issued by the [appropriate person or agency] in accordance with his [its] rules.

(b) Persons registered by the [appropriate person or agency] under this Act to manufacture, distribute, dispense, or conduct research with controlled substances may possess, manufacture, distribute, dispense, or conduct research with those substances to the extent authorized by their registration and in conformity with the other provisions of this Article.

(c) The following persons need not register and may lawfully possess controlled substances under this Act:

(1) an agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance if he is acting in the usual course of his business or employment;

(2) a common or contract carrier or warehouseman, or an employee thereof, whose possession of any controlled substance is in the usual course of business or employment;

(3) an ultimate user or a person in possession of any controlled substance pursuant to a lawful order of a practitioner or in lawful possession of a Schedule V substance.

(d) The [appropriate person or agency] may waive by rule the requirement for registration of certain manufacturers, distributors, or dispensers if he [it] finds it consistent with the public health and safety.

(e) A separate registration is required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances.

(f) The [appropriate person or agency] may inspect the establishment of a registrant or applicant for registration in accordance with the [appropriate person or agency's] rule.

COMMENT

This Section requires any person who engages in, or intends to engage in, the manufacture, distribution, or dispensing of controlled substances to be registered

by the State. Practitioners who administer, as that term is defined in Section 101(b), or who prescribe, will be required to register; however, under subsequent sections they may be exempt from the record-keeping requirements. By registering every individual dealing with controlled substances, the State will know who is responsible for a substance and who is dealing in these substances. The tighter registration requirements imposed by this Section are designed to close the gaps in State laws and thus eliminate many of these sources of diversion, both actual and potential.

Common and contract carriers, warehousemen, ultimate users, and agents of registrants are specifically exempted from the registration requirements since to require otherwise would be extremely burdensome and afford little increase in protection against diversion.

Annual registration is called for so that a licensee can be screened and the registration lists purified should the need arise. In addition, the annual registration requirement will be a form of check on persons authorized to deal in controlled substances.

SECTION 303. [*Registration.*]

(a) The [appropriate person or agency] shall register an applicant to manufacture or distribute controlled substances included in Sections 204, 206, 208, 210, and 212 unless he [it] determines that the issuance of that registration would be inconsistent with the public interest. In determining the public interest, the [appropriate person or agency] shall consider the following factors:

(1) maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels;

(2) compliance with applicable State and local law;

(3) any convictions of the applicant under any Federal and State laws relating to any controlled substance;

(4) past experience in the manufacture or distribution of controlled substances, and the existence in the applicant's establishment of effective controls against diversion;

(5) furnishing by the applicant of false or fraudulent material in any application filed under this Act;

(6) suspension or revocation of the applicant's Federal registration to manufacture, distribute, or dispense controlled substances as authorized by Federal law; and

(7) any other factors relevant to and consistent with the public health and safety.

(b) Registration under subsection (a) does not entitle a registrant to manufacture and distribute controlled substances in Schedule I or II other than those specified in the registration.

(c) Practitioners must be registered to dispense any controlled substances or to conduct research with controlled substances in Schedules II through V if they are authorized to dispense or conduct research under the law of this State. The [appropriate

person or agency] need not require separate registration under this Article for practitioners engaging in research with non-narcotic controlled substances in Schedules II through V where the registrant is already registered under this Article in another capacity. Practitioners registered under Federal law to conduct research with Schedule I substances may conduct research with Schedule I substances within this State upon furnishing the [appropriate person or agency] evidence of that Federal registration.

(d) Compliance by manufacturers and distributors with the provisions of the Federal law respecting registration (excluding fees) entitles them to be registered under this Act.

COMMENT

This Section sets out the criteria under which a State authority registers persons to engage in the various activities concerning controlled substances. There is required a showing by the applicant of the maintenance of adequate safeguards against diversion, of compliance with State and local laws, and of his previous experience in the manufacture or distribution of such substances. These criteria are almost identical to those which the Attorney General must consider in registering an applicant under the Federal Controlled Substances Act except for antitrust considerations, which were not considered applicable to the State control procedures. Thus, any particular applicant need meet only one set of criteria for both Federal and State registration.

In addition, registration under the Federal Controlled Substances Act will be deemed sufficient for registration under State law. Since the criteria for Federal and State registration are virtually identical, nothing would be served by requiring a registrant under Federal law to go through a similar procedure in registering under State law. Wasteful duplication would be the only result. Under the proposed system, a single form will suffice to register an applicant under both State and Federal law.

Practitioners are to be registered to prescribe or dispense substances in Schedules II through V, comprising all substances with recognized medical uses, if they are authorized to prescribe or dispense under the laws of the State. If those practitioners wish to conduct research in nonnarcotic substances in Schedules II through V, the State authority has within its discretion the right to require, or not require, a separate registration. It is felt that such permissive language will be most beneficial to those States who wish to keep close tabs on all those individuals who conduct research within their borders.

Practitioners who are registered under Federal law to conduct research with respect to Schedule I substances are permitted to conduct that research in a State solely upon notification to the appropriate State authority of a valid Federal registration.

SECTION 304. [*Revocation and Suspension of Registration.*]

(a) A registration under Section 303 to manufacture, distribute, or dispense a controlled substance may be suspended or revoked by the [appropriate person or agency] upon a finding that the registrant:

(1) has furnished false or fraudulent material information in any application filed under this Act;

(2) has been convicted of a felony under any State or Federal law relating to any controlled substance; or

(3) has had his Federal registration suspended or revoked to manufacture, distribute, or dispense controlled substances.

(b) The [appropriate person or agency] may limit revocation or suspension of a registration to the particular controlled substance with respect to which grounds for revocation or suspension exist.

(c) If the [appropriate person or agency] suspends or revokes a registration, all controlled substances owned or possessed by the registrant at the time of suspension or the effective date of the revocation order may be placed under seal. No disposition may be made of substances under seal until the time for taking an appeal has elapsed or until all appeals have been concluded unless a court, upon application therefor, orders the sale of perishable substances and the deposit of the proceeds of the sale with the court. Upon a revocation order becoming final, all controlled substances may be forfeited to the State.

(d) The [appropriate person or agency] shall promptly notify the Bureau of all orders suspending or revoking registration and all forfeitures of controlled substances.

COMMENT

This Section sets out the grounds upon which a State authority may revoke or suspend a registration. Subsection (a) sets out the criteria upon which a registration can be revoked or suspended during the year in which that particular registration is in force. In denial of registration renewal situations for manufacturers or distributors, the criteria in this subsection should not be used. Instead, the State authority should apply the broader criteria set out in Section 303(a) relating to initial registration.

Subsection (b) allows the State authority in its discretion to limit the revocation or suspension of a registration to a particular substance rather than revoking or suspending the whole registration. This will be especially effective where, for example, a manufacturer committed a criminal violation, but certain mitigating circumstances militate against removing his full registration. Instead, his right to manufacture a particular substance could be suspended or revoked. This would put him out of the business of manufacturing in the substance or schedule in which he committed the violation, but would not totally remove his livelihood.

Subsection (c) relates to forfeitures of controlled substances where the registrant who has the right to possess those substances has his registration revoked. This Section has purposely been drafted to be permissive rather than mandatory. Thus, for example, if the registration of a sole medical practitioner or a community pharmacy in a small town were revoked, the State authority could in its discretion allow the revoked registrant to sell those substances to a new owner-registrant so that the inhabitants of the particular town would not have to go without needed pharmaceutical supplies.

Upon a final order of revocation of a registration, the State must promptly notify the Federal Bureau of Narcotics and Dangerous Drugs. Such a provision is necessary since revocation of a State registration is grounds for denial, suspension, or revocation of a Federal registration.

SECTION 305. [*Order to Show Cause.*]

(a) Before denying, suspending or revoking a registration, or refusing a renewal of registration, the [appropriate person or agency] shall serve upon the applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended, or why the renewal should not be refused. The order to show cause shall contain a statement of the basis therefor and shall call upon the applicant or registrant to appear before the [appropriate person or agency] at a time and place not less than 30 days after the date of service of the order, but in the case of a denial or renewal of registration the show cause order shall be served not later than 30 days before the expiration of the registration. These proceedings shall be conducted in accordance with [insert appropriate administrative procedures] without regard to any criminal prosecution or other proceeding. Proceedings to refuse renewal of registration shall not abate the existing registration which shall remain in effect pending the outcome of the administrative hearing.

(b) The [appropriate person or agency] may suspend, without an order to show cause, any registration simultaneously with the institution of proceedings under Section 304, or where renewal of registration is refused, if he [it] finds that there is an imminent danger to the public health or safety which warrants this action. The suspension shall continue in effect until the conclusion of the proceedings, including judicial review thereof, unless sooner withdrawn by the [appropriate person or agency] or dissolved by a court of competent jurisdiction.

COMMENT

This Section requires the State authority to serve upon a registrant an order to show cause why his registration should not be revoked or suspended or his registration renewal refused prior to taking such action. The order will contain enough information to fully apprise the registrant of the charges against him and will be served at least 30 days before his current registration expires. All proceedings will be conducted under appropriate administrative procedures. If, during the pendency of an administrative hearing to deny a renewal registration, the registration runs out, this Section keeps the old registration in force until the administrative hearing is completed.

Subsection (b) allows the State authority, in cases of imminent danger to the public health or safety, to suspend the registration simultaneously with the institution of proceedings to revoke, suspend, or refuse a renewal. Such an emergency situation can occur when, for example, a practitioner, knowing that

action is being taken to revoke his registration, begins to buy and divert large quantities of controlled substances. Rather than having to wait until all administrative proceedings have been completed and allow substantial diversion of these substances, the State authority may act immediately to suspend the registration. It may then place all controlled substances under seal until the administrative hearing is completed.

SECTION 306. [*Records of Registrants.*] Persons registered to manufacture, distribute, or dispense controlled substances under this Act shall keep records and maintain inventories in conformance with the record-keeping and inventory requirements of Federal law and with any additional rules the [appropriate person or agency] issues.

COMMENT

This Section, which requires registrants to prepare inventories and records of all stocks of Schedule I through V substances, ties into the proposed Federal system and should prove to be more than adequate for State record-keeping purposes. By tying the State and Federal systems together, different "paper" requirements will be avoided and wasteful duplication eliminated. However, if a State sees a need for any additional recordkeeping or inventory requirements, this provision provides the appropriate State agency with the authority to promulgate those rules.

This Section is also intended to exempt those individuals exempted by Federal law from recordkeeping and inventory requirements.

SECTION 307. [*Order Forms.*] Controlled substances in Schedule I and II shall be distributed by a registrant to another registrant only pursuant to an order form. Compliance with the provisions of Federal law respecting order forms shall be deemed compliance with this Section.

COMMENT

This Section requires order forms for the distribution of any Schedule I or II substances. It, too, is tied into the proposed Federal system and compliance with the Federal order form requirements should be sufficient to fulfill any State order form requirements. Thus, economic waste resulting from duplication will again be avoided.

SECTION 308. [*Prescriptions.*]

(a) Except when dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, no controlled substance in Schedule II may be dispensed without the written prescription of a practitioner.

(b) In emergency situations, as defined by rule of the [appropriate person or agency], Schedule II drugs may be dispensed

upon oral prescription of a practitioner, reduced promptly to writing and filed by the pharmacy. Prescriptions shall be retained in conformity with the requirements of Section 306. No prescription for a Schedule II substance may be refilled.

(c) Except when dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, a controlled substance included in Schedule III or IV, which is a prescription drug as determined under [appropriate State or Federal statute], shall not be dispensed without a written or oral prescription of a practitioner. The prescription shall not be filled or refilled more than 6 months after the date thereof or be refilled more than 5 times, unless renewed by the practitioner.

(d) A controlled substance included in Schedule V shall not be distributed or dispensed other than for a medical purpose.

COMMENT

This Section draws on existing State and Federal law with the exception that emergency provisions have been added with regard to the filling of oral prescriptions. This was done in recognition of common accepted practice between physicians and pharmacists.

ARTICLE IV

[OFFENSES AND PENALTIES]

SECTION 401. [*Prohibited Acts A—Penalties.*]

(a) Except as authorized by this Act, it is unlawful for any person to manufacture, deliver, or possess with intent to manufacture or deliver, a controlled substance.

(1) Any person who violates this subsection with respect to:

(i) a controlled substance classified in Schedule I or II which is a narcotic drug, is guilty of a crime and upon conviction may be imprisoned for not more than [ ], or fined not more than [ ], or both;

(ii) any other controlled substance classified in Schedule I, II, or III, is guilty of a crime and upon conviction may be imprisoned for not more than [ ], fined not more than [ ], or both;

(iii) a substance classified in Schedule IV, is guilty of a crime and upon conviction may be imprisoned for not more than [ ], fined not more than [ ], or both;

(iv) a substance classified in Schedule V, is guilty of a crime and upon conviction may be imprisoned for not more than [ ], fined not more than [ ], or both.

(b) Except as authorized by this Act, it is unlawful for any person to create, deliver, or possess with intent to deliver, a counterfeit substance.

(1) Any person who violates this subsection with respect to:
(i) a counterfeit substance classified in Schedule I or II which is a narcotic drug, is guilty of a crime and upon conviction may be imprisoned for not more than [ ], fined not more than [ ], or both;
(ii) any other counterfeit substance classified in Schedule I, II, or III, is guilty of a crime and upon conviction may be imprisoned for not more than [ ], fined not more than [ ], or both;
(iii) a counterfeit substance classified in Schedule IV, is guilty of a crime and upon conviction may be imprisoned for not more than [ ], fined not more than [ ], or both;
(iv) a counterfeit substance classified in Schedule V, is guilty of a crime and upon conviction may be imprisoned for not more than [ ], fined not more than [ ], or both.

(c) It is unlawful for any person knowingly or intentionally to possess a controlled substance unless the substance was obtained directly from, or pursuant to, a valid prescription or order of a practitioner while acting in the course of his professional practice, or except as otherwise authorized by this Act. Any person who violates this subsection is guilty of a misdemeanor.

COMMENT

This Section designates the prohibited acts relating to unlawful manufacture and delivering of controlled substances, or possession with intent to manufacture or deliver such substances. The penalty structure is broken down according to the schedule of the substance involved and the particular unlawful act, since it is felt that trafficking offenses involving certain types of drugs constitute a greater danger to the public and are deserving of stiffer penalties. The actual sentence length for any particular offense has not been included since it is felt that such a designation is purely a State decision.

The term "delivery" as used in this Section is intended to include both dispensing and distribution as they are defined in Section 101.

Subsection (c) has been drafted specifically to provide for a lesser penalty for simple possession than is provided for the trafficking and illicit manufacturing type offenses under subsections (a) and (b). It is contemplated that subsections (a) and (b) will contain harsh penalties (felony, high misdemeanor, etc.); subsection (c) provides for misdemeanor (or comparable State term) treatment for the simple possession charge.

Finally, it should be noted that lawful possession of a Schedule V substance by ultimate users is not an offense. [See Section 302(c)(3)].

SECTION 402. [*Prohibited Acts B—Penalties.*]

(a) It is unlawful for any person:

(1) who is subject to Article III to distribute or dispense a controlled substance in violation of Section 308;

(2) who is a registrant, to manufacture a controlled sub-

stance not authorized by his registration, or to distribute or dispense a controlled substance not authorized by his registration to another registrant or other authorized person;

(3) to refuse or fail to make, keep or furnish any record, notification, order form, statement, invoice or information required under this Act;

(4) to refuse an entry into any premises for any inspection authorized by this Act; or

(5) knowingly to keep or maintain any store, shop, warehouse, dwelling, building, vehicle, boat, aircraft, or other structure or place, which is resorted to by persons using controlled substances in violation of this Act for the purpose of using these substances, or which is used for keeping or selling them in violation of this Act.

(b) Any person who violates this Section is guilty of a crime and upon conviction may be imprisoned for not more than [ ], fined not more than [ ], or both.

COMMENT

This Section defines those "commercial" offenses relating to registrants or other persons who unlawfully manufacture, distribute, or dispense controlled substances or fail to comply with the requirements of the Act.

Violation of subsection (a)(4) occurs when an inspector has an administrative inspection warrant, or is not required to have such a warrant under Section 502 (b)(4), and the person whose premises are to be inspected refuses admittance.

Subsection (a)(5) applies to all persons who knowingly keep or maintain any illegal establishment. Illegal establishments under this Section are intended to include not only stationary buildings, such as stores, shops, warehouses or dwellings and movable vehicles, such as boats or aircraft, but also intermediate structures such as trailers.

SECTION 403. [*Prohibited Acts C—Penalties.*]

(a) It is unlawful for any person knowingly or intentionally:

(1) to distribute as a registrant a controlled substance classified in Schedules I or II, except pursuant to an order form as required by Section 307 of this Act;

(2) to use in the course of the manufacture or distribution of a controlled substance a registration number which is fictitious, revoked, suspended, or issued to another person;

(3) to acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception or subterfuge;

(4) to furnish false or fraudulent material information in, or omit any material information from, any application, report, or other document required to be kept or filed under this Act, or any record required to be kept by this Act; or

(5) to make, distribute, or possess any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render the drug a counterfeit substance.

(b) Any person who violates this Section is guilty of a crime and upon conviction may be imprisoned for not more than [ ], or fined not more than [ ], or both.

COMMENT

This Section sets out the fraud offenses relating to the manufacture and distribution of controlled substances. This area of criminal activity was segregated from Section 401 because of the nature of these offenses and their effect, regardless of the drug involved, on the integrity of the regulatory system.

It should be noted that the acts or omissions set forth in subsection (a)(4) are not only a violation of this Act but also provide a basis for revocation or suspension of registration under Section 304.

SECTION 404. [*Penalties Under Other Laws.*] Any penalty imposed for violation of this Act is in addition to, and not in lieu of, any civil or administrative penalty or sanction otherwise authorized by law.

SECTION 405. [*Bar to Prosecution.*] If a violation of this Act is a violation of a Federal law or the law of another State, a conviction or acquittal under Federal law or the law of another State for the same act is a bar to prosecution in this State.

SECTION 406. [*Distribution to Persons Under Age 18.*] Any person 18 years of age or over who violates Section 401(a) by distributing a controlled substance listed in Schedules I or II which is a narcotic drug to a person under 18 years of age who is at least 3 years his junior is punishable by the fine authorized by Section 401(a)(1)(i), by a term of imprisonment of up to [twice] that authorized by Section 401(a)(1)(i), or by both. Any person 18 years of age or over who violates Section 401(a) by distributing any other controlled substance listed in Schedules I, II, III, IV, and V to a person under 18 years of age who is at least 3 years his junior is punishable by the fine authorized by Section 401(a)(1)(ii), (iii), or (iv), by a term of imprisonment up to [twice] that authorized by Sections 401(a)(1)(ii), (iii), or (iv), or both.

COMMENT

The Section is designed to impose stiffer penalties on those persons over eighteen years of age who distribute controlled substances to persons under

eighteen years of age. However, the recipient must be at least three years younger than the distributor before this Section comes into effect. The three year age differentiation is included to prevent imposition of the stiffer penalties in a case such as where a nineteen year old college student distributes two or three marihuana cigarettes to his seventeen year old roommate. In this situation, there is not the element of seduction so often found in the cases where the distributor and recipient are far apart in age.

[SECTION 407. [*Conditional Discharge for Possession as First Offense.*] Whenever any person who has not previously been convicted of any offense under this Act or under any statute of the United States or of any State relating to narcotic drugs, marihuana, or stimulant, depressant, or hallucinogenic drugs, pleads guilty to or is found guilty of possession of a controlled substance under Section 401(c), the court, without entering a judgment of guilt and with the consent of the accused, may defer further proceedings and place him on probation upon terms and conditions. Upon violation of a term or condition, the court may enter an adjudication of guilt and proceed as otherwise provided. Upon fulfillment of the terms and conditions, the court shall discharge the person and dismiss the proceedings against him. Discharge and dismissal under this Section shall be without adjudication of guilt and is not a conviction for purposes of this Section or for purposes of disqualifications or disabilities imposed by law upon conviction of a crime, including the additional penalties imposed for second or subsequent convictions under Section 408. [There may be only one discharge and dismissal under this Section with respect to any person.]]

COMMENT

This Section is designed to permit a judge to place a first offender on probation in lieu of sentencing him to prison. However, it is applicable only to cases involving simple possession of controlled substances and is available only once with respect to any person. It should also be noted that first offender treatment is not available as a matter of right, but rather is discretionary with the judge.

An additional aspect of this Section is that it provides for confidentiality of the defendant's record upon fulfilling all the terms and conditions of his probation. This will preclude any permanent criminal record from attaching to and following the individual in later life.

This Section, which goes beyond the provisions of the Youth Corrections Act by allowing for first offender treatment regardless of the defendant's age, should give judges added flexibility in dealing with this type of offender. This is particularly so in light of the fact that most of these individuals are either casual drug users or experimenters who would be unlikely to commit the offense again after their first encounter with the law.

This Section is bracketed so that States which have a general statutory provision allowing conditional discharge for first offenders need not use this Section. However, if that State provision does not cover simple possession of a controlled

substance, and in all other States which have no first offender treatment, this Section should be included.

[SECTION 408. [*Second or Subsequent Offenses.*]

(a) Any person convicted of a second or subsequent offense under this Act may be imprisoned for a term up to twice the term otherwise authorized, fined an amount up to twice that otherwise authorized, or both.

(b) For purposes of this Section, an offense is considered a second or subsequent offense, if, prior to his conviction of the offense, the offender has at any time been convicted under this Act or under any statute of the United States or of any State relating to narcotic drugs, marihuana, depressant, stimulant, or hallucinogenic drugs.

(c) This Section does not apply to offenses under Section 401(c).]

COMMENT

This Section is bracketed so that it may be used in States which choose to impose stiffer penalties on those persons who commit second and subsequent offenses under the Act. This stiffer second penalty provision, however, will not apply to offenses of simple possession under Section 401(c).

ARTICLE V

[ENFORCEMENT AND ADMINISTRATIVE PROVISIONS]

SECTION 501. [*Powers of Enforcement Personnel.*]

(a) Any officer or employee of the [appropriate agency] designated by the [appropriate person] may:

(1) carry firearms in the performance of his official duties;

(2) execute and serve search warrants, arrest warrants, administrative inspection warrants, subpoenas, and summonses issued under the authority of this State;

(3) make arrests without warrant for any offense under this Act committed in his presence, or if he has probable cause to believe that the person to be arrested has committed or is committing a violation of this Act which may constitute a felony;

(4) make seizures of property pursuant to this Act; or

(5) perform other law enforcement duties as the [appropriate person] designates.

COMMENT

The purpose of this Section is to insure that those individuals charged with the enforcement of the Act may be given full enforcement authority. Full en-

forcement authority, as opposed to authority restricted to offenses relating only to controlled substances, should give additional flexibility in the utilization of enforcement personnel within the State.

This Section does not give blanket authority to all members of a particular agency to carry weapons, execute and serve search warrants, make arrests, make seizures or perform other law enforcement duties. It does place discretion in the appropriate person or agency to select those field enforcement personnel who will enforce the act.

SECTION 502. [*Administrative Inspections and Warrants.*]

(a) Issuance and execution of administrative inspection warrants shall be as follows:

(1) A [judge of a State court of record, or any State magistrate] within his jurisdiction, and upon proper oath or affirmation showing probable cause, may issue warrants for the purpose of conducting administrative inspections authorized by this Act or rules hereunder, and seizures of property appropriate to the inspections. For purposes of the issuance of administrative inspection warrants, probable cause exists upon showing a valid public interest in the effective enforcement of this Act or rules hereunder, sufficient to justify administrative inspection of the area, premises, building or conveyance in the circumstances specified in the application for the warrant;

(2) A warrant shall issue only upon an affidavit of a designated officer or employee having knowledge of the facts alleged, sworn to before the judge or magistrate and establishing the grounds for issuing the warrant. If the judge or magistrate is satisfied that grounds for the application exist or that there is probable cause to believe they exist, he shall issue a warrant identifying the area, premises, building, or conveyance to be inspected, the purpose of the inspection, and, if appropriate, the type of property to be inspected, if any. The warrant shall:

(i) state the grounds for its issuance and the name of each person whose affidavit has been taken in support thereof;

(ii) be directed to a person authorized by Section 501 to execute it;

(iii) command the person to whom it is directed to inspect the area, premises, building, or conveyance identified for the purpose specified and, if appropriate, direct the seizure of the property specified;

(iv) identify the item or types of property to be seized, if any;

(v) direct that it be served during normal business hours and designate the judge or magistrate to whom it shall be returned;

(3) A warrant issued pursuant to this Section must be executed and returned within 10 days of its date unless, upon a showing of a need for additional time, the court orders otherwise. If property is seized pursuant to a warrant, a copy shall be given to the person from whom or from whose premises the property is taken, together with a receipt for the property taken. The return of the warrant shall be made promptly, accompanied by a written inventory of any property taken. The inventory shall be made in the presence of the person executing the warrant and of the person from whose possession or premises the property was taken, if present, or in the presence of at least one credible person other than the person executing the warrant. A copy of the inventory shall be delivered to the person from whom or from whose premises the property was taken and to the applicant for the warrant;

(4) The judge or magistrate who has issued a warrant shall attach thereto a copy of the return and all papers returnable in connection therewith and file them with the clerk of the [appropriate State court for the judicial district] in which the inspection was made.

(b) The [appropriate person or agency] may make administrative inspections of controlled premises in accordance with the following provisions:

(1) For purposes of this Section only, "controlled premises" means:

(i) places where persons registered or exempted from registration requirements under this Act are required to keep records; and

(ii) places including factories, warehouses, establishments, and conveyances in which persons registered or exempted from registration requirements under this Act are permitted to hold, manufacture, compound, process, sell, deliver, or otherwise dispose of any controlled substance.

(2) When authorized by an administrative inspection warrant issued pursuant to subsection (a) an officer or employee designated by the [appropriate person or agency], upon presenting the warrant and appropriate credentials to the owner, operator, or agent in charge, may enter controlled premises for the purpose of conducting an administrative inspection.

(3) When authorized by an administrative inspection warrant, an officer or employee designated by the [appropriate person or agency] may:

(i) inspect and copy records required by this Act to be kept;

(ii) inspect, within reasonable limits and in a reasonable

manner, controlled premises and all pertinent equipment, finished and unfinished material, containers and labeling found therein, and, except as provided in subsection (b)(5), all other things therein, including records, files, papers, processes, controls, and facilities bearing on violation of this Act; and

(iii) inventory any stock of any controlled substance therein and obtain samples thereof;

(4) This Section does not prevent the inspection without a warrant of books and records pursuant to an administrative subpoena issued in accordance with [insert appropriate State Code section], nor does it prevent entries and administrative inspections, including seizures of property, without a warrant:

(i) if the owner, operator, or agent in charge of the controlled premises consents;

(ii) in situations presenting imminent danger to health or safety;

(iii) in situations involving inspection of conveyances if there is reasonable cause to believe that the mobility of the conveyance makes it impracticable to obtain a warrant;

(iv) in any other exceptional or emergency circumstance where time or opportunity to apply for a warrant is lacking; or,

(v) in all other situations in which a warrant is not constitutionally required;

(5) An inspection authorized by this Section shall not extend to financial data, sales data, other than shipment data, or pricing data unless the owner, operator, or agent in charge of the controlled premises consents in writing.

COMMENT

The purpose of this Section is to codify certain recent United States Supreme Court decisions, in particular *Camara* v. *Municipal Court of the City and County of San Francisco*, 387 U.S. 523 (1967), *See* v. *City of Seattle*, 387 U.S. 541 (1967), and *Colonnade Catering Corp.* v. *U.S.*, 397 U.S. 72 (1970), with regard to inspection warrants.[1] The Section sets out in very careful terms the procedures and restrictions for obtaining and using an administrative inspection warrant. This is of vital importance to the States since they are involved in the regulation of the legitimate drug industry and must have the ability to inspect records, books and premises if access to them is denied. By having a carefully delineated code section dealing with administrative inspection warrants, law enforcement officers will be more certain of what is needed to obtain them and the courts can apply a uniform standard. Perhaps even more important, the industry being inspected will have more certainty as to its rights and obligations in this area.

[1] See also: *Kramer Grocery* v. *U.S.*, 294 F.Supp. 65 (1968); and *United States* v. *Stanack Sales Co.*, 387 F.2d 849 (1968).

It should be noted that the Supreme Court, in *Camara* v. *Municipal Court* spoke of the requirement of "probable cause" for issuance of an administrative inspection warrant. But the Court was not, however, speaking in terms of criminal probable cause, which would require a specific knowledge of the condition of the particular building to be inspected. Instead, rejecting the criminal probable cause argument, it required merely a valid public interest in the effective enforcement of a particular public health or safety act which justified the intrusion contemplated.

Although this Section codifies the Court's view for administrative inspection warrants, it in no way affects criminal probable cause as that phrase is defined under present criminal statutes or case law.

Finally, it should be noted that while Section 402(a)(4) makes it a violation of the Act to refuse entry into any premises for inspection, it is contemplated that such inspection will have been authorized under the rules set out in this Section.

SECTION 503. [*Injunctions.*]

(a) The [trial courts of this State] have [may exercise] jurisdiction to restrain or enjoin violations of this Act.

(b) The defendant may demand trial by jury for an alleged violation of an injunction or restraining order under this Section.

SECTION 504. [*Cooperative Arrangements and Confidentiality.*]

(a) The [appropriate person or agency] shall cooperate with Federal and other State agencies in discharging his [its] responsibilities concerning traffic in controlled substances and in suppressing the abuse of controlled substances. To this end, he [it] may:

(1) arrange for the exchange of information among governmental officials concerning the use and abuse of controlled substances;

(2) coordinate and cooperate in training programs concerning controlled substance law enforcement at local and State levels;

(3) cooperate with the Bureau by establishing a centralized unit to accept, catalogue, file, and collect statistics, including records of drug dependent persons and other controlled substance law offenders within the State, and make the information available for Federal, State and local law enforcement purposes. He [it] shall not furnish the name or identity of a patient or research subject whose identity could not be obtained under subsection (c); and

(4) conduct programs of eradication aimed at destroying wild or illicit growth of plant species from which controlled substances may be extracted.

(b) Results, information, and evidence received from the Bureau relating to the regulatory functions of this Act, including results of inspections conducted by it may be relied and acted

upon by the [appropriate person or agency] in the exercise of its regulatory functions under this Act.

(c) A practitioner engaged in medical practice or research is not required or compelled to furnish the name or identity of a patient or research subject to the [appropriate person or agency], nor may he be compelled in any State or local civil, criminal, administrative, legislative or other proceedings to furnish the name or identity of an individual that the practitioner is obligated to keep confidential.

COMMENT

The purpose of this Section is to establish a basis for increased cooperation and exchange of information among State, local, and Federal law enforcement agencies. Real implementation of these cooperative arrangements will provide for the first time a means of obtaining meaningful statistics on drug dependent persons and other controlled substance law offenders. There is a definite need to obtain these statistics if there is ever to be an accurate assessment of the total drug abuse problem in the United States. The intent of this section is to insure that both Federal and State agencies responsible for enforcement of these laws work in harmony and maximize their direction and efforts, rather than duplicate and overlap each other's activities.

SECTION 505. [*Forfeitures.*]

(a) The following are subject to forfeiture:

(1) all controlled substances which have been manufactured, distributed, dispensed or acquired in violation of this Act;

(2) all raw materials, products and equipment of any kind which are used, or intended for use, in manufacturing, compounding, processing, delivering, importing, or exporting any controlled substance in violation of this Act;

(3) all property which is used, or intended for use, as a container for property described in paragraphs (1) or (2);

(4) all conveyances, including aircraft, vehicles or vessels, which are used, or intended for use, to transport, or in any manner to facilitate the transportation, for the purpose of sale or receipt of property described in paragraph (1) or (2), but:

(i) no conveyance used by any person as a common carrier in the transaction of business as a common carrier is subject to forfeiture under this Section unless it appears that the owner or other person in charge of the conveyance is a consenting party or privy to a violation of this Act;

(ii) no conveyance is subject to forfeiture under this Section by reason of any act or omission established by the owner thereof to have been committed or omitted without his knowledge or consent;

(iii) a conveyance is not subject to forfeiture for a violation of Section 401(c); and,

(iv) a forfeiture of a conveyance encumbered by a bona fide security interest is subject to the interest of the secured party if he neither had knowledge of nor consented to the act or omission.

(5) all books, records, and research products and materials, including formulas, microfilm, tapes, and data which are used, or intended for use, in violation of this Act.

(b) Property subject to forfeiture under this Act may be seized by the [appropriate person or agency] upon process issued by any [appropriate court] having jurisdiction over the property. Seizure without process may be made if:

(1) the seizure is incident to an arrest or a search under a search warrant or an inspection under an administrative inspection warrant;

(2) the property subject to seizure has been the subject of a prior judgment in favor of the State in a criminal injunction or forfeiture proceeding based upon this Act;

(3) the [appropriate person or agency] has probable cause to believe that the property is directly or indirectly dangerous to health or safety; or

(4) the [appropriate person or agency] has probable cause to believe that the property was used or is intended to be used in violation of this Act.

(c) In the event of seizure pursuant to subsection (b), proceedings under subsection (d) shall be instituted promptly.

(d) Property taken or detained under this Section shall not be subject to replevin, but is deemed to be in the custody of the [appropriate person or agency] subject only to the orders and decrees of the [court having jurisdiction over the forfeiture proceedings]. When property is seized under this Act, the [appropriate person or agency] may:

(1) place the property under seal;

(2) remove the property to a place designated by him [it]; or

(3) require the [appropriate administrative agency] to take custody of the property and remove it to an appropriate location for disposition in accordance with law.

(e) When property is forfeited under this Act the [appropriate person or agency] may:

(1) retain it for official use;

(2) sell that which is not required to be destroyed by law and which is not harmful to the public. The proceeds shall

be used for payment of all proper expenses of the proceedings for forfeiture and sale, including expenses of seizure, maintenance of custody, advertising and court costs;

(3) require the [appropriate administrative agency] to take custody of the property and remove it for disposition in accordance with law; or

(4) forward it to the Bureau for disposition.

(f) Controlled substances listed in Schedule I that are possessed, transferred, sold, or offered for sale in violation of this Act are contraband and shall be seized and summarily forfeited to the State. Controlled substances listed in Schedule I, which are seized or come into the possession of the State, the owners of which are unknown, are contraband and shall be summarily forfeited to the State.

(g) Species of plants from which controlled substances in Schedules I and II may be derived which have been planted or cultivated in violation of this Act, or of which the owners or cultivators are unknown, or which are wild growths, may be seized and summarily forfeited to the State.

(h) The failure, upon demand by the [appropriate person or agency], or his [its] authorized agent, of the person in occupancy or in control of land or premises upon which the species of plants are growing or being stored, to produce an appropriate registration, or proof that he is the holder thereof, constitutes authority for the seizure and forfeiture of the plants.

COMMENT

This Section is designed to provide forfeiture provisions for those States which do not already have them and to revise those State forfeiture laws which have become obsolete and unenforceable over the years. Effective law enforcement demands that there be a means of confiscating the vehicles and instrumentalities used by drug traffickers in committing violations under this Act. The reasoning is to prevent their use in the commission of subsequent offenses involving transportation or concealment of controlled substances and to deprive the drug trafficker of needed mobility.

Until recently, the Federal Government adopted a policy of seizing vehicles belonging to defendants being prosecuted in State proceedings. The primary reason for this was that the States either had no forfeiture provisions or else they did not enforce them. However, this policy had to be discontinued, and, as a result, numerous vehicles which would be subject to forfeiture are no longer being confiscated. With comprehensive and effective forfeiture provisions, States may be less reluctant to implement them and begin confiscating the tools of the drug trafficker.

SECTION 506. [*Burden of Proof; Liabilities.*]

(a) It is not necessary for the State to negate any exemption or

exception in this Act in any complaint, information, indictment or other pleading or in any trial, hearing, or other proceeding under this Act. The burden of proof of any exemption or exception is upon the person claiming it.

(b) In the absence of proof that a person is the duly authorized holder of an appropriate registration or order form issued under this Act, he is presumed not to be the holder of the registration or form. The burden of proof is upon his to rebut the presumption.

(c) No liability is imposed by this Act upon any authorized State, county or municipal officer, engaged in the lawful performance of his duties.

SECTION 507. [*Judicial Review.*] All final determinations, findings and conclusions of the [appropriate person or agency] under this Act are final and conclusive decisions of the matters involved. Any person aggrieved by the decision may obtain review of the decision in the [appropriate State Court]. Findings of fact by the [appropriate person or agency], if supported by substantial evidence, are conclusive.

COMMENT

States which have adopted the Model State Administrative Procedures Act may wish to modify the language of this Section to conform to it or omit the Section entirely.

SECTION 508. [*Education and Research.*]

(a) The [appropriate person or agency] shall carry out educational programs designed to prevent and deter misuse and abuse of controlled substances. In connection with these programs he [it] may:

(1) promote better recognition of the problems of misuse and abuse of controlled substances within the regulated industry and among interested groups and organizations;

(2) assist the regulated industry and interested groups and organizations in contributing to the reduction of misuse and abuse of controlled substances;

(3) consult with interested groups and organizations to aid them in solving administrative and organizational problems;

(4) evaluate procedures, projects, techniques, and controls conducted or proposed as part of educational programs on misuse and abuse of controlled substances;

(5) disseminate the results of research on misuse and abuse of controlled substances to promote a better public understanding of what problems exist and what can be done to combat them; and,

(6) assist in the education and training of State and local law enforcement officials in their efforts to control misuse and abuse of controlled substances.

(b) The [appropriate person or agency] shall encourage research on misuse and abuse of controlled substances. In connection with the research, and in furtherance of the enforcement of this Act, he [it] may:

(1) establish methods to assess accurately the effects of controlled substances and identify and characterize those with potential for abuse;

(2) make studies and undertake programs of research to:

(i) develop new or improved approaches, techniques, systems, equipment and devices to strengthen the enforcement of this Act;

(ii) determine patterns of misuse and abuse of controlled substances and the social effects thereof; and,

(iii) improve methods for preventing, predicting, understanding and dealing with the misuse and abuse of controlled substances; and,

(3) enter into contracts with public agencies, institutions of higher education, and private organizations or individuals for the purpose of conducting research, demonstrations, or special projects which bear directly on misuse and abuse of controlled substances.

(c) The [appropriate person or agency] may enter into contracts for educational and research activities without performance bonds and without regard to [appropriate code section].

(d) The [appropriate person or agency] may authorize persons engaged in research on the use and effects of controlled substances to withhold the names and other identifying characteristics of individuals who are the subjects of the research. Persons who obtain this authorization are not compelled in any civil, criminal, administrative, legislative, or other proceeding to identify the individuals who are the subjects of research for which the authorization was obtained.

(e) The [appropriate person or agency] may authorize the possession and distribution of controlled substances by persons engaged in research. Persons who obtain this authorization are exempt from State prosecution for possession and distribution of controlled substances to the extent of the authorization.

COMMENT

This Section, setting out the education and research provisions, is designed to make it clear that education and research are an integral part of the total law enforcement effort. Broad language is used in order to provide maximum latitude.

Of primary importance are subsections (c) and (d) authorizing persons engaged in legitimate research to withhold the identities of research subjects and allowing the State to authorize possession and distribution of controlled substances. These provisions will tie into proposed Federal law and will allow legitimate researchers to carry on much needed research without fear of exposing either themselves or their research subjects to criminal prosecution.

It should be noted that a grant of Federal immunity would preempt any State grant or denial of immunity. However, the converse would not be true, and a researcher in possession of controlled substances under a State grant of immunity could be prosecuted under Federal law if the Federal government elected not to confer immunity. However, it is unlikely that this situation will arise.

ARTICLE VI

[MISCELLANEOUS]

SECTION 601. [*Pending Proceedings.*]

(a) Prosecution for any violation of law occurring prior to the effective date of this Act is not affected or abated by this Act. If the offense being prosecuted is similar to one set out in Article IV of this Act, then the penalties under Article IV apply if they are less than those under prior law.

(b) Civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of this Act are not affected by this Act.

(c) All administrative proceedings pending under prior laws which are superseded by this Act shall be continued and brought to a final determination in accord with the laws and rules in effect prior to the effective date of the Act. Any substance controlled under prior law which is not listed within Schedules I through V, is automatically controlled without further proceedings and shall be listed in the appropriate schedule.

(d) The [appropriate person or agency] shall initially permit persons to register who own or operate any establishment engaged in the manufacture, distribution, or dipsensing of any controlled substance prior to the effective date of this Act and who are registered or licensed by the State.

(e) This Act applies to violations of law, seizures and forfeiture, injunctive proceedings, administrative proceedings and investigations which occur following its effective date.

COMMENT

Subsection (d) is a provisional grandfather clause which provides for the automatic licensing of any person already licensed or registered by the State to engage in the manufacture, distribution, or dispensing of controlled substances on the Act's effective date. After that date, they will then be subject to the

annual renewal requirements and will have to meet all the requirements of Sections 302 and 303.

SECTION 602. [*Continuation of Rules.*] Any orders and rules promulgated under any law affected by this Act and in effect on the effective date of this Act and not in conflict with it continue in effect until modified, superseded or repealed.

SECTION 603. [*Uniformity of Interpretation.*] This Act shall be so applied and construed as to effectuate its general purpose to make uniform the law with respect to the subject of this Act among those States which enact it.

SECTION 604. [*Short Title.*] This Act may be cited as the Uniform Controlled Substances Act.

SECTION 605. [*Severability.*] If any provision of this Act or the application thereof to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the Act which can be given effect without the invalid provision or application, and to this end the provisions of this Act are severable.

COMMENT

This Section is included for States which have no general saving statute. If a State has such a statute, with a comparable severability clause, Section 605 should be excluded.

SECTION 606. [*Repealers.*] The laws specified below are repealed except with respect to rights and duties which matured, penalties which were incurred and proceedings which were begun before the effective date of this Act:

[List statutes to be repealed].

SECTION 607. [*Effective Date.*] This Act shall take effect on the first day after the beginning of the seventh month following the date of its enactment.