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PO Box 144
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June 27, 2018

Drug Enforcement Administration
Attn: Administrator
8701 Morrissette Drive
Springfield, VA 22152

Re: Citizen's Petition Submitted Pursuant to 21 C.F.R. §1308.43 ("Initiation of Proceedings for Rulemaking") requesting rulemaking changes to 21 C.F.R. § 1305.01, *et seq*. "General Requirements" re: orders for Schedule I and II controlled substances) and 21 C.F.R. §1305.29 ("Reporting to DEA") and other relevant provisions of Title 21, Code of Federal Regulations, Part 1300-end.

Dear Administrator:

The undersigned petitioner, on behalf of DrugWatch International, a 501c3 non-profit drug abuse prevention and education organization incorporated in the state of Illinois, hereby petitions the Administrator of the Drug Enforcement Administration (DEA) to initiate proceedings for rulemaking in the manner and for the purposes described herein.

The petitioner requests the Administrator of DEA to initiate proceedings for rulemaking to amend existing regulations in Title 21, Code of Federal Regulations, Part 1300-end, to require that business activities registered with DEA as retail pharmacies and hospitals be required to use the DEA Controlled Substances Ordering System (CSOS) when placing orders for controlled substances with authorized suppliers.

Secondly, the petitioner requests the Administrator of DEA to initiate proceedings for rulemaking to require that a digitally signed copy of the CSOS electronic order for controlled substances be sent to DEA by the purchaser at the same time as the CSOS electronic order is sent to the supplier.

Attached hereto and constituting a part of this petition are the following:

I. Background information pertaining to DEA information systems used to monitor the distribution of controlled substances purchased by retail pharmacies and hospitals from drug manufacturers and wholesale.

(A/B) Proposed rules in the forms proposed by the petitioner.

(A1/B1) Grounds upon which the petitioner relies for issuance of each proposed rule.

Respectfully submitted,

John J. Coleman, PhD
Petitioner

I. Background

Two decades ago, the Drug Enforcement Administration (DEA) undertook to acquire a secure online system to be used by commercial registrants to order Schedule I[1] and Schedule II controlled substances. The Controlled Substance Ordering System (CSOS) became operational in May 2005. Prior to this date, DEA required that all orders for Schedule I and Schedule II controlled substances had to be submitted on an agency-supplied official order form (DEA Form-222). To ensure the integrity of the ordering process, the Form-222 was serially numbered and issued with the name, address, and registration number of the registrant, the authorized activity, and authorized schedules of the registrant.[2]

In accordance with the applicable regulations in force then and now, copies of the trifold Form-222 order form must be maintained for two years by the customer and supplier, with the latter sending a completed copy of the form to the local DEA field office by the end of the month in which the order is filled.[3]

This paper-based ordering system was – and continues to be – inefficient. It also is obsolete[4] in this age of information automation. As we show later in this petition, it likely contributed to the industry's perception that submitting these forms to DEA was little more than a *pro forma* exercise posing little risk for ignoring regulations requiring suppliers to identify and report suspicious orders to DEA. Moreover, if there was this perception of little risk in failing to report suspicious orders, it probably was inevitable that some distributors would assume that there was little risk in filling them.

Throughout the 1980s and 1990s, as former DEA officials report, local DEA offices in areas where registered manufacturers and distributors were located received monthly batches of completed Form-222s that they inventoried, bundled and stored in bankers boxes. In 2003 alone, the agency issued more than six million individual order forms to some 98,000 registrants.[5] Given the volume of incoming forms and the paucity of trained personnel in field offices to analyze them, it is no wonder the industry chose to ignore the law.

By 1999, it was obvious that long-overdue improvements in DEA's monitoring of the industry had to be made. PEC Solutions, Inc., an information technology firm and government contractor, was awarded a contract to design a secure online system to process and track certain drug transactions between registrants. The new system would be called the Controlled Substances Ordering System or CSOS. The timing for this was right because of the Government Paperwork Elimination Act of 1999[6]

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[1] Schedule I controlled substances are included in these regulations although they generally are not marketed to retail pharmacies or hospitals. Schedule I Controlled substances are available only to persons holding a special research registration. Because this petition exclusively pertains to drugs in the retail and hospital setting, it will forego mentioning Schedule I controlled substances in describing current and proposed rules unless otherwise specified. The rule changes requested in this petition are intended to apply to medicinal controlled substances only.

[2] See: 21 CFR §1305.11(d). (2018 edition).

[3] See: 21 CFR §1305.13(a) & 21 CFR §1305.17(c). (2018 edition).

[4] For example, the 2018 edition of the CFR describes the procedure for executing the Form 222: "A purchaser must prepare and execute a DEA Form 222 simultaneously in triplicate by means of interleaved carbon sheets that are part of the DEA Form 222. DEA Form 222 must be prepared by use of a typewriter, pen, or indelible pencil." (21 CFR §1305.12(a)).

[5] See: Department of Justice, Drug Enforcement Administration. Final Rule: Electronic Orders for Controlled Substances; 21 CFR Parts 1305 and 1311; Federal Register/Vol. 70, No. 62/Friday, April 1, 2005/Rules and Regulations, p.16902. Washington, D.C.

[6] See: P.L. 105-277, Title XVII.

that, among other things, required federal agencies by October 21, 2003, to provide regulated entities with the option of submitting required records electronically. DEA's decision to modernize also was being encouraged by industry registrants whose automated business systems were incompatible with DEA's inefficient and obsolete paper-based system.

On June 27, 2003, after conducting a series of pilot studies for its new automated CSOS, DEA issued a Notice of Proposed Rulemaking to permit the use of electronic orders, digitally signed, in place of the Form-222. Two years later, on April 1, 2005, DEA issued a Final Rule to announce the formal establishment of the CSOS. The effective date was May 31, 2005 for the new system to be implemented nationwide.[7]

In its 17-page Final Rule, DEA discussed 11 public comments received in response to its proposed rule to establish the CSOS. Comments were submitted by major trade associations representing pharmacies and distributors as well as individual companies and one vendor.[8] The comments were supportive of the new system and some offered suggestions for improvements that DEA accepted and included in its Final Rule.

In its Final Rule, DEA provided a detailed analysis of the estimated costs over ten-years comparing the paper form with the electronic version. The cost of the paper system was estimated to be $2,699,913,000 and the cost of the electronic system was estimated to be $298,086,000 – about 11 percent of the cost of the paper system.[9] These estimates were based on the number of hours and labor costs of using each of these systems for the anticipated volume of orders over ten years.

To ease the burden of these changes on the industry and to comply with the Government Paperwork Elimination Act of 1999, the use of the CSOS by the regulated entities (i.e., manufacturers, distributors, pharmacies, etc.) was optional. Even today, more than a decade and a half later, it remains optional. Use of the Form-222 is still acceptable, although most commercial suppliers have switched to the use of the CSOS. To use the CSOS each individual purchaser must enroll with DEA to acquire a CSOS digital certificate that, in turn, certifies the purchaser's digital signature for signing and authorizing electronic orders submitted through the CSOS.

While the CSOS was intended primarily to facilitate the ordering and reporting of Schedule II drug transactions, DEA permits its use for ordering Schedule III to V drugs and even non-controlled substances when also ordering Schedule II drugs. And unlike the paper form that limited the number of items that could be ordered on a single form, the CSOS allows for an unlimited number of items to be specified on a single order form.

DEA's Final Rule clearly made the case for how the industry would benefit from adopting the new system. Left unstated was that the new system also would significantly benefit the DEA by providing, perhaps for the first time, an efficient and effective way to track distributions of Schedule II drugs.

Not to be overlooked in its importance to this petition is a statement in the Final Rule indicating that DEA envisioned completely phasing out the use of the paper form over ten years and "assumed that

[7] Ibid. (p. 16902)
[8] Ibid. (p. 16903)
[9] Ibid. (p. 16909)

implementation [*ed.:* of the CSOS] would be phased in over the first five years (*i.e.*, it would be five years before all registrants were using the electronic order system)."[10,11]

Thus, by DEA's own reckoning, as of May 2010, the CSOS was to become the official and exclusive order form for transactions involving controlled substances, and by May 2015, the paper order form would no longer be used. To date, neither of these two projected actions has been realized.

Given the seriousness of the current prescription opioid abuse crisis, DrugWatch International, Inc., has identified reasonable modifications to existing regulations in Part 1300 of Title 21, Code of Federal Regulations (CFR) that, it believes, will prevent future violations of the CSA by registrant manufacturers, distributors, and dispensers of controlled substances. The rule changes being proposed are the result of years of research into what only can be described as a collapse of the government's responsibility to prevent – by its own estimates[12] - the diversion of hundreds of millions of dosage units of controlled substances, mostly Schedule II drugs such as oxycodone and hydrocodone, over the past two decades, a time when it is estimated that hundreds of thousands of Americans lost their lives as a result fatal overdoses involving prescription opioids.[13]

The CSA authorizes the Attorney General to register manufacturers and distributors of controlled substances and to determine that such registration is consistent with the public interest (21 USC 823(a)). In addition, the Attorney General is authorized to promulgate rules and regulations relating to the control of the manufacture, distribution, and dispensing of controlled substances (21 USC 821). These authorities have been delegated by the Attorney General to the Administrator of the DEA (21 USC 871(a)). Thus, the initiation of proceedings for rulemaking being proposed in this petition by DrugWatch International, Inc., is wholly within the authority of the Administrator of DEA to initiate pursuant to 21 USC 871(a), 21 CFR 1308.43, and relevant provisions of 5 USC 5.

(A) Proposed Rule 1 in a form proposed by petitioner DrugWatch International, Inc.:

Business activities registered by DEA as retail pharmacies and hospitals are required by (effective date to be determined) to use the DEA Controlled Substances Ordering System (CSOS) for placing orders for Schedule II, III, IV and V controlled substances with suppliers. For convenience, when using the CSOS official order form to order controlled substances, purchasers may include non-controlled substances in the same order form.

(A1) Grounds on which the petitioner relies for the issuance of this rule

[10] Ibid. (p. 16909)
[11] Parenthetical phrase in original.
[12] See: Figure 1.
[13] According to the CDC, more than 630,000 people died from a drug overdose in the U.S. between 1999 and 2016. More than half (55.6%) of these deaths involved an *opioid*. Both prescription opioids and illicit opioids such as fentanyl analogs and heroin are included in these numbers. Until 2010, the CDC data show that heroin-related overdose deaths were relatively stable from year to year (below 1 death per 100,000 population), about the same as the death rate from fentanyl until 2013. Since 2010 and 2013, heroin and fentanyl have driven up the rate of opioid overdose deaths to more than 6 per 100,000 population. Still, it is a reasonable estimate that between 1999 and the present, prescription opioids have been involved in hundreds of thousands of overdose deaths and that most deaths involved oxycodone and hydrocodone, often in combination with other psychoactive substances, including alcohol. See: Understanding the Epidemic: Opioid Overdose. Centers for Disease Control and Prevention. Atlanta, 2017. (Available: https://www.cdc.gov/drugoverdose/epidemic/index.html).

This is the first of two proposed rule changes that, together, are aimed at further closing the "closed system" of the drug supply chain intended by Congress when it enacted the CSA in 1970. When the CSA was drafted, the microprocessor or what today is known to us as the *computer* was in its infancy. Multifold forms, using interleaved carbon sheets, were industry and government standard for keeping track of important data. The DEA Form-222 was a model of excellence for its time – just as the big steel cars of the 1970s were models of automotive excellence and used by government agents in the enforcement of the law. While the big steel cars have been replaced by modern versions that are more efficient and reliable, the Form-222 continues on.

In 1970, when the CSA was enacted, Americans spent $5.5 billion for prescription drugs, including controlled substances. In 2017, Americans spent $338.1 billion for prescription drugs and this is expected to increase to $360.2 billion for 2018. This enormous growth in spending for prescribed drugs has been matched by similar growth in the information technology sector that supports the drug industry. The use of a paper form like the Form-222 may have been adequate for the 1970s but like those big steel cars we mentioned above, its day has come and gone, and it is time to move into the computer age when it comes to tracking sales and distributions of controlled substances.

Thus, DrugWatch International, Inc., hereby petitions the DEA Administrator to initiate rulemaking proceedings to require, by a date certain, that all registrants currently approved to use the Form-222 be required to terminate such use and place orders for all classes of controlled substances using the CSOS electronic order form. In the event that smaller registrant firms do not have the resources to upgrade their technology to enable them to use the CSOS, they should be "grandfathered" in and permitted to use the Form-222. As of a date certain, however, there should be no more registrations approved for manufacturers, distributors, and pharmacies that do not agree to use the CSOS for transactions of all classes of controlled substances.

While this is a significant departure from the present arrangement, it comes not without adequate justification as evidenced by the current prescription opioid abuse crisis and the recent history of DEA's enforcement efforts to address the diversion of controlled substances from legitimate to illegitimate channels. A brief synopsis of that history is worth mentioning as part of the grounds supporting the changes being requested herein.

In 2005, DEA began a series of regulatory investigations aimed at wholesale distributors of controlled substances that failed to inform DEA of suspicious orders received from pill mills, rogue Internet pharmacies and others suspected of diverting controlled substances. While significant in many ways, this initiative occurred too late in the crisis to have much effect in reducing the morbidity and mortality associated with the diversion and abuse of prescription opioids.

The initial run of DEA investigations of distributors yielded quick results. Besides data from DEA's Automation of Reports and Consolidated Orders System (ARCOS) that tracks distributions of controlled substances, information obtained from the distributors themselves often showed conclusively how frequently and how cavalierly they had ignored the law over many years as they supplied millions of dosage units of opioids to illicit pill mills and unregistered Internet pharmacies while, of course, failing to report the orders to DEA as suspicious. In fact, making these cases was so easy, and the evidence – already in hand via ARCOS and corroborated by company records obtained by subpoena or administrative search warrant – so voluminous, that within the first three years of the DEA's initiative against distributors, the agency was able to bring charges against each of the *Big Three* wholesale drug distributors: Cardinal Health, AmerisourceBergen, and McKesson. These companies, among the top 15 American companies in earnings, according to Fortune Magazine, were

charged by DEA with failing to report suspicious orders and thereby failing to prevent the diversion of controlled substances. Industry reports show that the Big Three distributors handle 85 percent or more of the nation's prescription drug supply as well as providing other services for the industry.

Despite overwhelming evidence of egregious wrongdoing and, in some instances, specific evidence of criminal violations by named company employees[14] and responsible corporate officials, these cases were settled out of court with modest civil fines and non-punitive settlement agreements. (See Figure 1) This "soft" approach did not work. Within five years of settling with the government, two of the Big Three were charged again by DEA with repeat offences. The third of the Big Three also was charged seven years after its initial settlement agreement. Each was permitted to pay another modest fine, sign another settlement agreement, and agree to accept brief suspensions of DEA registrations for one or more distribution facilities.

Apart from the time and litigation costs and the imposition of relatively modest fines, DEA's actions had virtually no economic effect on the Big Three companies because each has dozens of distribution facilities scattered throughout the U.S. and each facility is individually registered with DEA. As government lawyers advised a court reviewing a motion by Cardinal Health to overturn a DEA immediate suspension order (ISO) in 2012:

> "Cardinal has 25 distribution facilities that currently hold DEA registrations, of which Lakeland is only one (other distribution centers include Greensboro, North Carolina; Madison, Mississippi; and Denver, Colorado). The ISO is limited to Plaintiff's Lakeland facility, and thus, even in the absence of an injunction, it will remain free to distribute controlled substances from these and any other of its facilities that also hold the requisite DEA registration. The most that will occur is that Plaintiff may have to re-route controlled substances through Plaintiffs' other distribution facilities."[15] [emphasis added]

To be sure, the role of the wholesale drug distributor is vital in keeping the drug supply chain flowing efficiently to the nation's 200,000 pharmacies, hospitals, and long-term care facilities. The Healthcare Distribution Alliance (HDA), an organization representing the interests of drug distributors, has recommended to DEA the establishment of an online system through which distributors could report suspicious orders in a standardized fashion.[16] Although the law in question has been on the books for decades, the regulations and DEA policies do not specify how suspicious orders are to be reported to the local DEA field office. The HDA also recommends that the system be accessible to state law enforcement authorities, as well as state boards of pharmacy.

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[14] 21 USC §842(c)(1), the statutory provision often charged for a reporting violation, provides for a civil penalty. A subsequent provision at 21 USC §842(c)(2)(A), however, provides for a criminal penalty, *viz.*: "If a violation of this section is prosecuted by an information or indictment which alleges that the violation was committed knowingly and the trier of fact specifically finds that the violation was so committed, such person shall, except as otherwise provided in subparagraph (B) of this paragraph, be sentenced to imprisonment of not more than one year or a fine under title 18, or both." (US Code 2018 edition) DEA evidence presented in court in some cases showed that reporting violations were *knowingly* committed by specifically named company employee(s).

[15] See*: Cardinal Health Inc. v. Eric Holder, Jr., Attorney General, et al*. US District Court, District of Columbia, Case 1:12-cv-00185-RBW; Document 14; Filed 02/10/12; Page 39 of 49. Washington, D.C., 2012.

[16] See: Letter, dated February 16, 2018, to DEA Acting Administrator Robert Patterson from HDA President and CEO John M. Gray, re: "Need for Universal Suspicious Orders Database."

The HDA has good reason to be concerned about this issue. Since 2006, more than a dozen of its members have been charged by DEA with failing to report suspicious orders to the agency. (See Figure 1)

Major DEA Regulatory Actions Against Distributors and Other Supply Chain Entities Between 2006 and 2017

Distributor	Date	Drug	Amount	Disposition	DEA Registration(s)
Southwood Pharm.	2006	Hydrocodone	8.7m d.u.	MOA	1 Restored
Cardinal Health	2007	Hydrocodone	>8m d.u.	$34m Fine/MOA	3 Restored
AmerisourceBergen	2007	Hydrocodone	3.8m d.u.	MOA	1 Restored
McKesson	2008	Hydrocodone	~3m d.u.	$13.25m Fine/MOA	6 Restored
Masters Pharm.	2009	Hydrocodone	>4m d.u.	$0.5m Fine	1 Restored
Sunrise Wholesale	2010	Oxycodone	n/a	n/a	Surrendered
Harvard Medical Grp.	2010	Oxycodone	>13m d.u.	$8m Fine/MOA	1 Restored
KeySource Medical	2010	Oxycodone	~48m d.u.	$0.32m Fine/MOA	1 Suspended/Revoked
Omnicare[a]	2012	Various CS	Unk.	$50m Fine	Unaffected
CVS	2012	Various CS	Unk.	$11m Fine	Unaffected
Cardinal Health	2012	Oxycodone	>13m d.u.	$44m fine/MOA[e]	1 Suspended (2 Yrs.)
Walgreens	2013	Various CS	Unk.	$80m Fine/MOA	7 Susp. 12-16 Mos.
UPS[b]	2013	Various CS	Unk.	$40m Fine	Unaffected
FedEx[c]	2014	Various CS	Unk.	Case Dismissed 6/16	n/a
CVS Health	2015	Various CS	Unk	$22m Fine	2 Revocations
Miami-Luken, Inc.	2015	Hydrocodone/Oxycodone	>20m d.u.	In litigation at USCA 6th Cir.[h]	n/a
McKesson	2015	Various CS	Unk	$150m Fine/MOA[f]	4 Suspended 1-3 Yrs.
Masters Pharm.	2015	Oxycodone	>6.5m d.u.	DEA Final Order[d]	1 Revocation
Mallinckrodt	2017	Oxycodone	500m d.u.	$35m Fine, MOA[G]	Unaffected

Omnicare's fine was for violations of CSA by its pharmacy division. [b.] UPS, for purposes of this case, was considered a common carrier and not a DEA registrant; fine was in return for nonprosecution agreement that stipulated allegations of unlawful profits derived from conducting business with illegal Internet pharmacies. [c.] The FedEx Case was dismissed by the court on a motion by the Government on June 17, 2016. [d.] This case is before the United States Court of Appeals for District of Columbia Circuit (Case 15-1335) where oral arguments were held on 01/12/2017. [e.] Imposed December 2016. [f.] Imposed January 2017. [g.] Settled April 2017. [h.] M-L filed subpoena on DEA AJJ for docs, denied and appealed to USDC, moved to USCA 6th Cir after DEA's decision to quash subpoena denied (May 2018).
Note: m = million; d.u. = dosage unit; MOA= memorandum of agreement. Public Sources: U.S. District & Appeals Court files (PACER), DEA /DOJ press releases.

Figure 1[17]

Rarely are DEA charges contested in court because the evidence is solid and often based, in part, on the accused company's own sales records obtained by subpoena or warrant. Occasionally, a company may challenge the DEA's use of its authority to suspend a registration without notice. For example, in the second Cardinal Health case, company lawyers asked the court to overturn DEA's Immediate Suspension Order because, they argued, there was no *imminent* danger:

> "DEA's own delay in pursuing this matter confirms that Cardinal Health's continued registration—for the time required to adjudicate the matter before the DEA—poses no imminent danger. The ISO relies on sales of oxycodone in 2008, 2009, 2010, and 2011. Alleged conduct dating back years, however, even if potentially relevant to an Order to Show Cause ('OSC'), obviously cannot credibly be said to pose an imminent danger."[18]

Although DEA prevailed, Cardinal Health's arguments were not without merit. The evidence produced by DEA did indeed show that the charges leading up to the issuance of the ISO related to more than four years of non-compliance by Cardinal Health's Lakeland, Florida, distribution facility. Evidence from DEA's ARCOS showed that between 2008 and 2011, Cardinal Health failed to report to DEA suspicious orders of oxycodone amounting to more than 13 million dosage units that were

[17] Adapted and updated from: Coleman JJ. The supply chain of medicinal controlled substances: addressing the Achilles heel of drug diversion. *J Pain Palliat Care Pharmacother*. 2012;26(3):233-250.
[18] *Cardinal Health, Inc., v. Eric Holder, Jr., Attorney General, et al*. US District Court, District of Columbia, Case 1:12-cv-00185-RBW, Document 16, filed 02/13/12 (p. 3 of 27). 2012; Obtained via PACER (Restricted).

shipped to pharmacy customers in Florida, four of whom, it was alleged, diverted the drugs.[19]

Add to this the fact that the 2012 charges against Cardinal Health involved the same location and the very same violations as were charged against the company in 2007, meaning, in effect, that the company continued to violate the law even while under the terms of its prior settlement agreement with the government.

The leniency of the government in the cases noted in Figure 1 notwithstanding, the one indisputable fact that is clear in each of them is that far too much time elapsed and far too many violations occurred *before* DEA intervened. It is not the purpose of this petition to deal with the question of why it took two, three, four, or more years of persistent non-compliance before DEA acted. Let it be noted, however, that the relevant provisions of the law regarding the charges filed in these cases do not require such a broad scope or volume of evidence.[20]

What makes these delays even more troubling is the reality that during the time that these companies were unlawfully shipping hundreds of millions of dosage units of controlled substances, mostly opioids, to pill mills, rogue Internet pharmacies and others, thousands of persons throughout America were becoming addicted to, and dying from, prescription opioids obtained from pill mills and rogue Internet pharmacies.

The first rule being proposed here would dramatically and permanently change this. In effect, proposal (A) is the first part of a two-part strategy to eliminate not only the delay factor in these cases, but also – and this is even more important – to *prevent* future crimes like the ones that the DEA tried to address in the list of cases in Figure 1.

The CSOS has been operational for more than a decade and, from all outward appearances, it is viewed favorably by the industry. It is a secure and timely system shared by DEA and the industry for managing and monitoring transactions of controlled substances. The rules proposed in this petition are not expected to be opposed by the industry, primarily because the changes will affect only four classes of commercial registrants: manufacturers, distributors, retail pharmacies, and hospitals. Most, if not all, of these registrants (with the possible exception of small, independent pharmacies) already use the CSOS for ordering controlled substances.

ARCOS data for calendar year 2017 show that retail pharmacies accounted for 95.3 percent and hospitals accounted for 4.7 percent of all oxycodone distributed in the U.S. As for hydrocodone, retail pharmacies accounted for 94.5 percent and hospitals 5.3 percent of all U.S. distributions. With respect to morphine, retail pharmacies accounted for 90.8 percent and hospitals 9 percent of all U.S. distributions. Between them, pharmacies and hospitals last year distributed about 99 percent of the major opioids reaching the public, with pharmacies far and away leading the pack with 94 percent of all opioids distributed. (See Figure 2)

[19] In concert with the action against Cardinal Health, DEA also suspended the registrations of four pharmacy customers that had received unlawful shipments of controlled substances from Cardinal Health over the course of the four years in question.

[20] See, for example: 21 USC § 823(b) and 21 CFR § 1301.74(b).

U.S. SUMMARIES FOR RETAIL DRUG PURCHASES BY GRAMS WT, JANUARY 1, 2017 TO DECEMBER 31, 2017						
	PHARMACIES	HOSPITALS	PRACTITIONERS	TEACHING INSTITUTIONS	MID-LEVEL PRACTITIONERS	NARC. TRMT PROGRAMS
OXYCODONE	47,011,064.69	2,304,878.19	28,176.16	0.45	2,115.38	n/a
HYDROMORPHONE	1,170,184.67	219,365.42	7,106.71	50.18	49.23	1.24
HYDROCODONE	25,462,919.24	1,416,206.57	55,614.87	123.82	784.77	n/a
METHADONE	2,740,629.73	261,694.80	1,843.58	127.27	359.73	11,686,565
MORPHINE	15,051,540.45	1,497,374.40	19,208.81	133.35	1,087.72	n/a
OXYMORPHONE	1,088,551.12	9,931.06	559.89	0.54	13.92	n/a
TAPENTADOL	5,311,412.25	89,393.88	901.14	0.00	102.93	n/a
FENTANYL BASE	285,983.07	36,364.38	2,068.16	15.81	67.23	n/a
Source: DEA: Automation of Reports and Consolidated Orders System (ARCOS), 2017.						

Figure 2

As mentioned, the first rule being proposed in this Petition would require retail pharmacies and hospitals to use the CSOS for ordering all scheduled drugs. The importance of this rule change becomes clear when viewed with its companion rule change requested and described below.

(B) Proposed Rule 2 in a form proposed by petitioner DrugWatch International, Inc.:

Whenever a CSOS order for controlled substances is submitted by a registrant to a supplier, a digitally signed copy of the order must be sent electronically and simultaneously to DEA by the customer. The present requirement that a supplier must furnish DEA an executed copy of the completed CSOS order form within two business days of filling it remains in effect.

(B1) Grounds on which the petitioner relies for the issuance of this rule

The key change in the second proposed rule is the timing of the submission of the CSOS order form to DEA. Currently, the regulation requires that the supplier must send a copy of the completed CSOS order form to DEA within two business days of filling it and shipping the drugs to the customer. Under the proposed rule change, the supplier would still be obligated to send DEA a completed copy of the CSOS order form within two days of filling it. In effect, DEA would be receiving two copies of the electronic order form: once when the customer sends it, and again when the order is completed and the supplier has shipped the drugs to the customer. This effectively more securely closes the "closed system" envisioned by Congress in passing the CSA.

By virtue of the language in the current regulation at 21 CFR §1305.13(d)[21], DEA plays a passive role in regulating the distribution of controlled substances. This, as we note elsewhere, has proved to be inefficient and ineffective in halting diversion, particularly by distributors and pharmacies. Under the current regulation, DEA does not have the ability to identify a suspicious order, if has not been reported, until *after* the order has been filled and the drugs delivered to the customer. As we discussed above, the length of time between the first violation and DEA's intervention can be as long as four years or more, during which time enough drugs have been diverted to cause serious and irreversible harm.

[21] "d) The supplier must retain Copy 1 of the DEA Form 222 for his or her files and forward Copy 2 to the Special Agent in Charge of the Drug Enforcement Administration in the area in which the supplier is located. Copy 2 must be forwarded at the close of the month during which the order is filled. If an order is filled by partial shipments, Copy 2 must be forwarded at the close of the month during which the final shipment is made or the 60-day validity period expires." (21 CFR §1305.13(d))

What is proposed herein would change this paradigm and provide DEA with the authority to prevent these crimes from occurring in the first place – clearly a better approach than waiting years to catch up with a non-compliant registrant long after it has diverted - or failed to prevent the diversion of - millions of doses of controlled substances.

Discussion & Conclusion

Moving from a passive to an active posture with respect to monitoring orders for controlled substances, as requested by this petition, would provide several ancillary benefits besides preventing large-scale drug diversion. With the proposed rules in effect, DEA could move quickly to restructure its monitoring program to meet current and future regulatory needs. It is time, for example, to enlist advanced information technology to address commercial diversion of controlled substances. The inability of the government to curtail the epidemic of prescription opioid abuse was as much the fault of obsolete surveillance systems as the fault of an industry that ignored laws that until 2005 were rarely, if ever, enforced.

When it comes to implementing a regulatory policy that seeks to prevent, rather than correct, infractions, there are at least two models worth considering. The first is the National Instant Criminal Background Check System used to prevent sales of firearms to purchasers that the law prohibits from buying and owning a firearm. The applicable regulations for this system are found at 28 CFR § 25, *et seq.*

Before selling a firearm covered by this statute, a federal firearms licensee (FFL) must call a toll-free number to check the background and eligibility of the buyer to lawfully purchase a firearm. The system is managed by the Federal Bureau of Investigation (FBI) that will perform a background check of the prospective buyer and advise the FFL to proceed with the sale, delay the sale (pending the receipt of additional information), or deny the sale because the prospective buyer is barred by statute from owning a firearm.

By denying a sale for cause, the government is using its regulatory authority to prevent a crime, namely, the purchase of a firearm by a person not permitted to own it. Contrast the potential chaos that would ensue if, instead of a system to *prevent* the sale, the regulation was written to require the FFL to submit a completed report to the FBI only *after* the sale of the gun was completed – as we have in the case of regulations pertaining to sales of controlled substances.

The second model is the Combat Methamphetamine Epidemic Act of 2005 (CMEA). The control of non-prescription medicinal products containing pseudoephedrine, a List I chemical, is necessary to prevent the illicit conversion of this drug into methamphetamine, a Schedule II stimulant. Under the CMEA, a purchaser of pseudoephedrine tablets from a retail seller, such as a pharmacy, must provide photo identification to a store employee who, in turn, must record the buyer's identification and the details of the proposed purchase. As passed, the CMEA required that all retailers of pseudoephedrine products had to maintain a logbook containing the details of each sale and the identification of the purchaser.

Retailers considered the logbook requirement to be time-consuming and complicated. Within months of the Act's passage, software vendors specializing in automated systems for businesses adapted their popular pharmacy software to facilitate using the card-swipe readers in the stores to record sales data and the identification and signature of the purchaser. Sales data were communicated to a state-

managed computer via dedicated lines and secure portals. DEA issued a rule change to permit using the automated system in place of the CMEA's logbook requirement. In addition, software vendors were able to program a "stop-sale" feature to alert the retailer not to make the sale if it would exceed the customer's daily or 30-day purchase limit.

These regulatory changes pertaining to the sales of pseudoephedrine products worked and were credited by DEA with reducing the number of fixed methamphetamine labs and the availability of domestically produced methamphetamine. They would not have worked as well without the rapid processing of information to prevent the sale. The paper logbook as it was proposed in the CMEA was not unlike the Form-222 in that it was a passive record that could do little after an improper sale other than document its occurrence.

These two examples show that preventing an unlawful transaction – in one case a firearm and in the other a precursor for making methamphetamine – can be far more effective than relying on a passive system that can only establish after the fact that a crime was committed. The cost differential between active and passive systems is significant. Yes, there may be high start-up costs in software, training, obtaining certification, and the need for additional personnel. But, over time, the savings from reducing crime and its social consequences far outweigh the added start-up costs of the active system.

Assuming the rulemaking changes contained in this petition are enacted by DEA, the agency's CSOS software could be configured to identify items in an electronic CSOS order that appear to meet one or more of the criteria for being suspicious, as listed in the regulation. Since all orders must contain the individual DEA registration numbers for the customer and distributor, designing or adapting existing CSOS software programs to track specific drugs by their national drug code number, ordered by specific registrants and distributed by specific registrants, and then weighing all these data against the purchaser's historical buying patterns for the drug(s) in question, seems achievable with existing technology.

Unlike a manufacturer or a distributor that has only its own transaction records to assess whether an incoming order is suspicious, the CSOS and ARCOS contain confidential proprietary information showing each registrant-customer's aggregate volume of controlled substances purchased within any given period and from which registrant-distributor or registrant-manufacturer. While DEA's protected information cannot be shared with the registrant community to assist it in identifying suspicious orders, it surely can be - and should be - used by DEA in its automated systems for this purpose.

The CSOS computer, once configured to recognize an incoming suspicious order, could be programmed to send an automated response back to the purchaser and the supplier. This response would not interfere in the transaction other than to serve as a prompt to the parties that the system has flagged an anomaly that needs to be resolved. This, in turn, would give the parties an opportunity to address the issue to their (and DEA's) satisfaction.

Credit card companies use a similar prompting process when an atypical purchase enters the card holder's account. The automated email prompt to the account holder generally will simply note the "suspicious" charge and advise that the card holder may disregard the notice if the charge is legitimate. If using a similar program for alerting registrants to an order for controlled substances that is flagged by the CSOS computer as suspicious, the prompt might be more descriptive of the criterion or criteria triggering the alert.

An important aspect of this approach is that it brings DEA into the transaction at the very beginning of the ordering process, when the official CSOS order is placed – *not* after the order has been filled and the drugs reach their destination. Even though the cognitive party representing DEA in this proposed scenario may be a computer, it does not matter. Like an empty police car parked on the highway, the deterrence factor of its presence is not lost on those who happen to see it as they drive by.

It is somewhat remarkable that the paper-based Form-222 has lasted this long. Its continued use in a largely paperless business world is superseded in amazement only by the paper prescription format used by some prescribers of controlled substances, a practice first mandated more than a century ago by the Harrison Narcotic Tax Act of 1914.

In 1970, when the CSA was enacted, there were only 21 drugs mentioned by name in Schedule II, 10 drugs in Schedule III, 11 drugs in Schedule IV, and 5 drugs in Schedule V, for a total of 81 controlled substances approved for medical use in the U.S.[22] The latest edition (2018) of the CFR lists 62 drugs in Schedule II, 22 drugs in Schedule III, 75 drugs in Schedule IV, and 11 drugs in Schedule V, for a total of 170 controlled substances approved for medical use in the U.S.[23]

As we mentioned earlier in this petition, Americans spent $5.5 billion on prescription drugs in 1970, the same year as the CSA was enacted, although there is no assertion of relevance to these two facts. This was the equivalent of $35.7 billion in today's dollars, according to the U.S. Labor Department's Bureau of Statistics. In 2018, Americans will spend an estimated $360.2 billion on prescription drugs. This represents a 909 percent increase in *real* dollar spending for prescription drugs between 1970 and 2018. While data are not available to show the prescribing volume of opioids in 1970, versus what it is today, it is reasonable to assume that the size of the increase in spending for prescription drugs reflects a similar upward trend in the U.S. – especially in view of data showing that there were only 81 scheduled medicinal drugs in 1970, compared with 170 today.

This suggests that if the Form-222 ever had any usefulness in tracking the distribution of Schedule II drugs – perhaps, when the CSA was enacted and when the market for prescription drugs and, presumably, controlled substances, was much smaller - that time, we believe, has long passed. We believe that the case for ending the use of the paper Form-222 has been made by data presented in this petition.

What is being proposed as a replacement provides a method to prevent the crimes of the past two decades that in large part caused today's opioid abuse crisis. By any measure, the industry was at fault for failing to comply with regulations requiring manufacturers and distributors to identify and report suspicious orders for controlled substances. For its part, DEA was at fault for maintaining an ineffective and obsolete paper-based ordering system to monitor the distributions of Schedule II drugs after the fact.

According to DEA's aforementioned Final Rule establishing the CSOS and permitting electronic orders for controlled substances, the ARCOS system, DEA's flagship database for tracking transactions of controlled substances, apparently in 2005 had not yet been fully automated. In a parenthetical comment in the Final Order, the following is stated:

[22] See: United States Code. Controlled Substances Act, Title II, 21 USC 801, Pub.L. 91-513, 84 Stat. 1242. 1970.
[23] See: 21 CFR §1308.11 (2018 edition).

> "DEA notes that ARCOS is preparing to allow electronic filing of reports; when this occurs, DEA plans to develop a process by which the summary reports can be accepted as a substitute for ARCOS reporting for Schedule I and II substances, with the usual ARCOS provisions for filing corrections."[24]

Remarkably, in 2005, when DEA began its special project to investigate manufacturers and distributors for failing to report suspicious orders and for failing to prevent drug diversion, the agency still lacked an effective system to identify on a timely basis commercial registrants operating in violation of the law. As of May 2005, when the CSOS electronic order form was being phased-in for optional use instead of the paper form to order Schedule II drugs, the agency was receiving ARCOS data from registrants in paper spreadsheets or on electronic media. The ARCOS database, perhaps the agency's most important source of drug distribution data, was not yet functional to the point of allowing commercial registrants to submit their quarterly ARCOS reports electronically. These substandard and inefficient data systems no doubt hampered the agency's ability to curb the rising incidence of prescription drug abuse in a timely fashion.

On the DEA CSOS website, the following graphic depicts how the current CSOS system works, beginning with the pharmacy/purchaser: (See Figure 3)

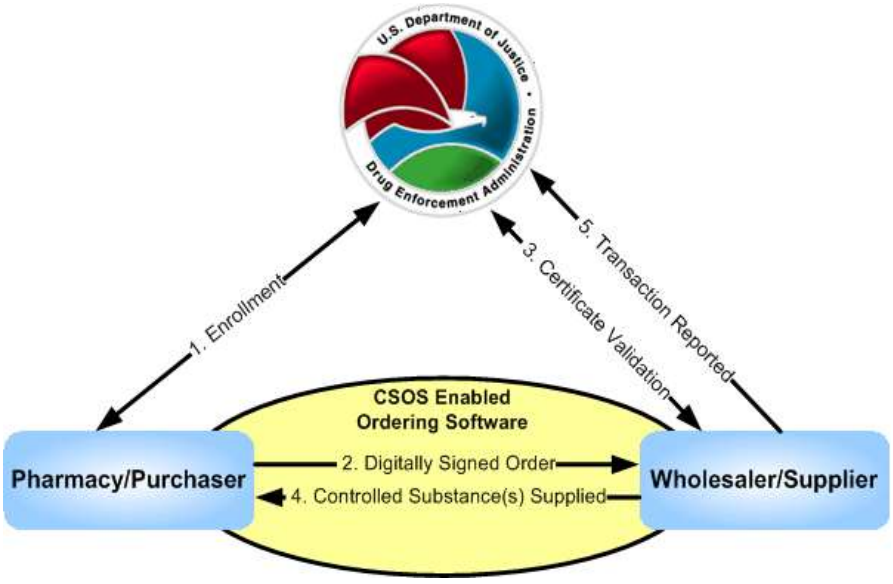

Figure 3

Below is the same schematic showing how the system will work when one additional step – the step petitioned for herein by the proposed rule changes – is taken by the Pharmacy/Purchaser to send a copy of the CSOS electronic order form to DEA and the recipient *at the same time*. (See Figure 4)

[24] See: Department of Justice, Drug Enforcement Administration. Final Rule: Electronic Orders for Controlled Substances; 21 CFR Parts 1305 and 1311; Federal Register/Vol. 70, No. 62/Friday, April 1, 2005/Rules and Regulations, p.16902. Washington, D.C.

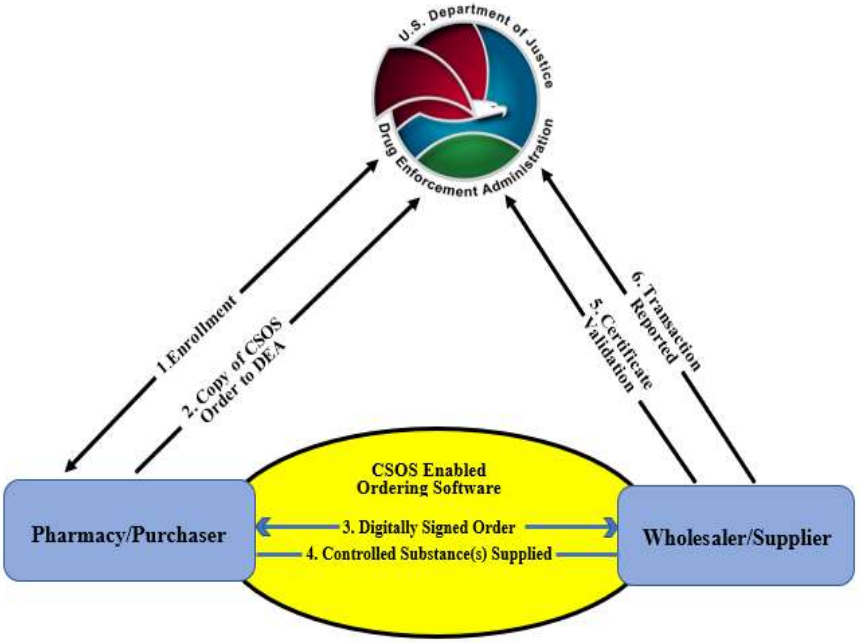

Figure 4

To be fair, understanding the design and workings of the systems discussed in this petition is difficult for the average person to comprehend. Even within the DEA itself, these systems are perhaps only fully understood by the technicians and operators that work with them. Thus, the undersigned fully anticipates and accepts that some of the changes asked for in this petition may need modification along the way before they can be finalized in a formal Notice of Proposed Rulemaking.

If technical or other changes are needed, the petitioner believes that, at a minimum, the core concepts presented herein should dictate the final version of the requested rulemaking changes. These core concepts include: 1) that the Form-222 be retired and phased out in a timely fashion; 2) that it be mandatory for all registrants authorized to purchase or distribute controlled substances to use the CSOS system; 3) that the CSOS form must be used for transactions of all schedules of controlled substances; 4) that DEA is sent a digitally signed electronic copy of the purchaser's prepared CSOS order form at the same time that it is submitted to the supplier; and 5) that a completed copy of the CSOS form be sent to DEA by the supplier within two business days of the order being filled.

We believe that moving to an all-automated electronic system for managing ARCOS and CSOS is long overdue, given the significance of the prescription drug abuse problem facing America today. According to the Fiscal Year 2018 federal budget submitted to Congress by the President, the U.S. will spend $27.8 billion this year on drug control. For the most part, the information systems used by federal agencies to plan and carry out our drug control strategies are woefully inadequate. The changes proposed herein represent just one small step in the right direction toward bringing these systems into the 21st century.

If enacted by DEA, the rule changes requested by this petition will not only reduce large scale drug diversion by commercial registrants, but also facilitate improved information sharing between DEA and the regulated entities, as proposed in recently introduced Senate bills, S. 2837 ("Preventing Drug Diversion Act of 2018") and S.2838 ("Using Data to Prevent Opioid Diversion Act of 2018"). Both bills have bipartisan support, as well as support from the industry's principal lobbying arm, the Healthcare Distribution Alliance. To its credit, DEA recently agreed to work with state attorneys

generals and boards of pharmacy in sharing ARCOS data. This is a good start, but to be successful, joint efforts like this and proposals contained in the pending Senate bills, will require fully automated data systems and improved surveillance programming, as recommended in this petition.

The drug industry has been criticized far and wide for its past crimes, ranging from criminal fraud to civil regulatory infractions of the type discussed herein and depicted in Figure 1. According to media reports, the district court for the Northern District of Ohio has been tasked with processing some 400 lawsuits brought by cities, counties and Native American tribes against opioid manufacturers and alleging various state and tribal law violations. The court has indicated that it would prefer that the parties reach settlement rather than proceed to a trial that would consume enormous resources and time. Special masters have been appointed by the court to recommend what might be done to resolve these cases and how this type of crisis can be prevented from happening again.[25]

Given the above, we believe that the timing is right for initiating rulemaking proceedings to enact the changes described in this petition. We also believe that the industry and the district court in Ohio would welcome an expanded role for DEA in monitoring prefilled orders for controlled substances. Some or all of the additional cost for this expanded role should be recoverable through increases in commercial registration fees paid by manufacturers, distributors, pharmacies and hospitals. Currently, DEA registration fees are quite modest for business sectors ranked among the highest revenue earners in America: Manufacturers: $3,047/year; Distributors: $1,523/year; Pharmacies: $731/3 years; and Hospitals: $731/3 years.[26]

It has been six years since DEA increased these registration fees. Under provisions of 21 USC §886(a) ("Diversion Fee Account"), DEA is authorized to use the fees charged to the registrant community to pay for the operation of the agency's diversion control program, *viz*.: "Fees charged by the Drug Enforcement Administration under its diversion control program shall be set at a level that ensures the recovery of the full costs of operating the various aspects of that program."[27] It would appear that a sensible bargain might be reached between DEA and the sectors of the industry whose fees would be raised to recover any additional costs to the agency for implementing the rules and systems proposed herein.

Commercial registrants may well prefer to spend funds for higher tax-deductible registration fees, than risk having to expend far more money in non-tax-deductible fines for regulatory infractions that, we believe, would be reduced or eliminated by the changes we suggest and request herein. Lastly, we believe that enacting the rules proposed in this petition will better serve the public interest by reducing prescription drug abuse.

Respectfully submitted on behalf of DrugWatch International, Inc.,

John J. Coleman, PhD
President
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[25] See: "Can This Judge Solve the Opioid Crisis?" Jan Hoffman, reporter, *The New York Times,* March 5, 2018.
[26] See: 21 CFR § 1301.13 (2018 edition).
[27] See: 21 USC § 886(a)(1)(C) [2018 edition].