Hercules
your ethical wholesaler

Comments on Proposed
National Standards for the
Licensure of
Wholesale Drug Distributors and
Third-Party Logistics Providers

Preliminary Note

Hercules Pharmaceuticals ("Hercules") recognizes the work performed by members of the U.S. Senate and the House of Representatives, Food & Drug Administration ("FDA"), the Department of Justice ("DOJ"), State Attorneys General, the National Association of Boards of Pharmacy ("NABP") with its constituent-member regulators, select portions of the industry, and the national media to strive towards making the United States pharmaceutical supply chain safe, ethical, and compliant.

Broader Context of the United States Pharmaceutical Supply Chain

The U.S. pharmaceutical supply chain is a critical national asset that concurrently implicates important public health policy and vital national economic interests. If the market is permitted to function properly, and if federal and state regulators are permitted to regulate correctly, the pharmaceutical supply chain shall fortify our nation against public health crises,[1] against criminals,[2] and against foreign geopolitical adversaries.[3]

Hercules Pharmaceuticals

Hercules is a nationally licensed primary[4] wholesale distributor accredited by the National Association of Boards of Pharmacy ("NABP"). Hercules serves on the Board of National Association of Specialty Pharmacy ("NASP") and its President serves on the Board of Directors for the Partnership for DSCSA Governance ("PDG").

Hercules exclusively purchases pharmaceuticals from manufacturers and exclusively sells pharmaceuticals to entities that are licensed to dispense or administer these drugs directly to patients.[5] As a matter of internal compliance and ethics, Hercules does not buy drugs from, or sell drugs to, other pharmaceutical wholesalers as this practice (i)

---

[1] Recent history highlights the fact that infectious disease pandemics will continue to emerge and affect the U.S. population, including by straining the supply chain. Though COVID-19 is the most recent and salient example, related illnesses such as SARS-CoV-1 [2002-03] and MERS-CoV [2012-13] underscore the fact that disease threats will continue to impact the United States.

[2] *See infra,* nn. 23–27.

[3] *See* Adm. James G. Foggo III, *Germs: The Seventh Domain of Warfare*, 146 PROCEEDINGS, U.S. NAVAL INST. (Apr. 2020) https://www.usni.org/magazines/proceedings/2020/april/germs-seventh-domain-warfare ("[W]e must be mindful that we may be ***entering a new era of pandemics***, either introduced unwittingly or ***weaponized by enemies seeking to inflict damage***. ***To protect our national security, we must improve our ability to fight pandemics***—germs, the seventh domain of warfare.") (emphasis added).

[4] Susan Thaul, CONG. RES. SERV., R43106, 4 PHARMACEUTICAL SUPPLY CHAIN SECURITY (2013) ("Distributors that predominantly buy prescription medicines from the manufacturers and predominantly distribute them directly to health care providers such as hospitals and pharmacies are called 'primary' distributors.") https://crsreports.congress.gov/product/pdf/R/R43106/5.

[5] 159 CONG. REC. S8024 (2013) [statement of Sen. Bennet (D-CO)] ("The normal chain moves drugs from the manufacturer to a wholesaler to a pharmacy.") https://www.congress.gov/113/crec/2013/11/14/CREC-2013-11-14-pt1-PgS8024.pdf.

Hercules Pharmaceuticals, Inc. 27 Seaview Boulevard, Port Washington, New York 11050
Phone: 1-212-390-8577 Fax: 1-212-390-8578 legal@herculesrx.com

increases the risk that drugs are adulterated through excursions in environmental conditions during transit; and (ii) is the gateway practice for gray market sales[6] and other more complex financial schemes.[7]

Hercules is dedicated to upholding the highest standard of ethics and integrity in the pharmaceutical supply chain, and as an ATP firmly supports the FDA's goal of creating a safe and secure pharmaceutical supply chain under a regulatory paradigm which transparently allocates compliance obligations, promotes the DSCSA's mandate of transparency, and allows for pharmaceutical supply chain auditability.[8] Concurrently, to manifest policy goals underlying the DSCSA and other compliance regimes, Hercules has created a highly evolved, carefully calibrated, pharmaceutical supply chain compliance program called the Gatekeeper Compliance Program™.

Hercules is privileged in working with the FDA on this matter and we respectfully submit our comments on its two recent draft guidance documents.

Executive Summary

Almost ten years after the passage of the DSCSA, the criminal placement of adulterated, counterfeit and mislabeled medicines continue. The overarching cause of this continuing failure is due to a significant gap between the stated legislative intent underling the DSCSA versus the DSCSA as it was written.

While the legislative history of the DSCSA evidences an intent to create a truly transparent and auditable supply chain, paradoxically the statutory language appears, at core junctures, calibrated to hamper these goals. As written, the DSCSA, instead fosters and favors opacity and continues the trend of regulatory permissiveness towards gray market transactions and wholesaler-to-wholesaler trade. Core flaws in the DSCSA text include the saleable returns loophole which obligates the laundering of data concerning prior ownership, confidentiality provisions which prevent the upstream transmission of downstream tracing information for the purposes of audit and compliance, and the non-abolition of wholesaler-to-wholesaler (secondary distribution) transactions despite their perennial implication in providing criminals entry into the legitimate supply chain.

The FDA's proposed codification of the 5% rule will further widen the gray market loopholes by permitting unlicensed wholesaling devoid of track and trace compliance obligations.

The FDA should also use the proposed national standard initiative to analyze harmful levels of concentration in the commercial distribution sector of pharmaceutical supply chain.

Authorized third-party auditors who will be responsible for the pre-licensing inspection process will have access to licensee trade secrets in the form of proprietary compliance programs and know-how, these individuals must serve under bulletproof nondisclosure and noncompete agreements prohibiting them from working for wholesalers or 3PLs.

---

[6] *See id*. ("In the last decade this lack of oversight has created an enormous gray market in the United States of America.").
[7] *See id.* ("The more times a drug goes back and forth and changes hands, the more opportunities criminals find to enter the system.").
[8] 159 CONG. REC. S8075 (2013) [statement of Sen. Harkin (D-IA)] ("We have also set in motion a revolution in the distribution of pharmaceuticals— within a decade we will know exactly how our drug products travel through the often-complicated distribution system so that we can identify counterfeit and adulterated drugs before they get into American medicine cabinets. By passing the Drug Quality and Security Act, we have taken an important step to improve American families' access to lifesaving drugs and medical devices.").

Last, the supply chain needs to be concurrently managed by federal and state authorities and in a manner that leverages all federal and state regulators.

The Current Regulatory Initiative

On February 4, 2022, the FDA promulgated a proposed rule entitled National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers[9] ("Proposed Standards") pursuant to its obligation under the Drug Supply Chain Security Act ("DSCSA") to set national standards for the licensure of prescription drug wholesale distributors ("WDs") and third-party logistics providers ("3PLs").[10] These rules seek to establish a national ***licensure*** standard for pharmaceutical wholesale distribution and 3PLs.

Licensure, under the DSCSA, functions as a condition precedent to entering the market for the interstate distribution of pharmaceuticals in the United States. It thus serves an important gatekeeping function, as the DSCSA restricts interstate commerce in pharmaceuticals to ***authorized trading partners*** ("ATPs"),[11] i.e., those who are licensed.[12] Stated otherwise, ***licensure imbues a trading partner with the authority and privilege necessary to engage in the interstate distribution of pharmaceuticals in the U.S.***

Licensure is a fulcrum for federal and state governments to leverage the manifestation of important public policy goals including ethics, compliance, and safety in the pharmaceutical supply chain.

The licensing and traceability standards, in a large part, are meant to keep criminal behavior out of the pharmaceutical supply chain. The U.S. has long wrestled with a startingly opaque and criminally accessible pharmaceutical supply chain[13] and it was a clearly stated goal of Congress in passing the DSCSA to fix that.

---

[9] National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers, 87 Fed. Reg. 6708 (proposed Feb. 4, 2022) (to be codified at 21 C.F.R. pts. 10, 12, 16, & 205) (docket no. FDA-2020-N-1663) (hereinafter Proposed Standards).

[10] *Id.* at 6709. "[T]the Drug Supply Chain Security Act (DSCSA), includes provisions designed to strengthen the integrity of the pharmaceutical distribution supply chain[, including] section 204 . . . [which] amends section 503(e) of the FD&C Act (21 U.S.C. 353(e)), which requires licensure of prescription drug wholesale distributors, . . . and adds section 583 to the FD&C Act (21 U.S.C. 360eee–2), which requires FDA to establish by regulation national standards for the licensure of prescription drug wholesale distributors. Section 205 of the DSCSA adds section 584 to the FD&C Act (21 U.S.C. 360eee–3), which requires licensure of third-party logistics providers and requires FDA to establish, by regulation, national standards for the licensure of third-party logistics providers."

[11] 21 U.S.C. § 360eee–1(b)(3) ("[T]he trading partners of a manufacturer may be only authorized trading partners."); 21 U.S.C. § 360eee-1(d)(3) ("[T]he trading partners of a dispenser may be only authorized trading partners.").

[12] 21 U.S.C. § 360eee(2)(B) ("The term 'authorized' means . . . in the case of a wholesale distributor, having a valid license under State law or section 360eee-2 of this title, in accordance with section 360eee-1(a)(6) of this title, and complying with the licensure reporting requirements under section 353(e) of this title."). *See also* 21 U.S.C. § 360eee(9)(A) ("The term 'licensed' means . . . in the case of a wholesale distributor, having a valid license in accordance with section 353(e) of this title or section 360eee-1(a)(6) of this title."); 21 U.S.C. § 360eee-1(a)(6) ("Notwithstanding section 360eee(9)(A) . . . , until the effective date of the [federal] wholesale distributor licensing regulations . . . the term 'licensed' or 'authorized', as it relates to a wholesale distributor . . . shall mean a wholesale distributor with a valid license under State law.").

[13] *See* KATHERINE EBAN, DANGEROUS DOSES 164 (2005) ("It was a huge loophole that allowed any big distributor to launder the origin of substandard medicine."); *see also*, *infra*, nn. 23–27.

The Legislative and Public Policy Goals of the DSCSA

The following are floor statements of US Senators and Representatives regarding the DSCSA: (*emphasis added*)

> "Securing our Nation's pharmaceutical supply chain is extremely important … . When anyone takes a prescribed medication, he or she should ***have full confidence that the medication is as prescribed and that no counterfeit or adulterated drug has entered the supply chain***."[14]
>
> "… ***within a decade we will know exactly how our drug products travel through the often-complicated distribution system*** so that we can identify counterfeit and adulterated drugs before they get into American medicine cabinets."[15]
>
> "[The DSCSA] ***establishes a comprehensive, electronic, interoperable framework for tracing the distribution history of every individual unit that passes through the drug supply chain. The effect of this part of the bill is to establish a 'chain of custody' or 'pedigree' for each prescription drug dispensed to patients***. Should a drug be diverted, this 'chain of custody' will provide important information to Federal regulators when counterfeit drugs are detected in the supply chain."[16]
>
> "[The DSCSA] ***raises the bar for wholesale distributors . . . Pharmacists cannot determine with any certainty where a drug has been and whether it has been secured and safely stored on its way to a pharmacy***. . . . ***The normal chain moves drugs from the manufacturer to a wholesaler to a pharmacy***.[17]
>
> "[The DSCSA] will establish an electronic, interoperable system at the Federal level ***that tracks each package of drugs at the unit level and that involves the entire supply chain***. This will help prevent Americans from being harmed by counterfeit and substandard medicines."[18]
>
> "***This bill ensures that we can trace a particular drug from its manufacturer all the way to the pharmacy***. It will allow consumers to buy prescription medications … that … are safe, legal, and free of counterfeit or substandard ingredients. … ***This is one of the basic functions of government: making sure that markets work by ensuring that no one cuts corners that the customer can't see or that put someone's family at risk***." [19]

These statements of legislative intent indicate the Congressional goal to establish a pharmaceutical track and trace system that is not only robust and secure, but comprehensive as to the drugs it includes and complete as to the transactions tracked for those drugs. Congress clearly viewed this as necessary to effectuate its public policy goals and set a timeline to accomplish them within 10 years.

---

[14] 159 CONG. REC. H5962 (2013) (statement of Rep. Latta).
[15] 159 CONG. REC. S8075 (2013) (statement of Sen. Harkin).
[16] 159 CONG. REC. S8074 (2013) (statement of Sen. Feinstein).
[17] 159 CONG. REC. S8025 (2013) (statement of Sen. Bennet).
[18] 159 CONG. REC. H5961 (2013) (statement of Sen. Waxman).
[19] 159 CONG. REC. S8075 (2013) (statement of Sen. Warren).

The Pharmaceutical Supply Chain Before the DSCSA

Prior to the enactment of the DSCSA in 2013, the legitimate pharmaceutical supply chain was beset with counterfeit and adulterated medicines introduced by gray market actors. Famously identified in the book *Dangerous Doses*,[20] temperature-sensitive specialty medications were being stored in the backrooms of strip clubs, garages, and residences, devoid of environmental controls, and transported in the uncooled trunks of passenger vehicles by gray market diverters. Adulterated and counterfeit medicine was being reintroduced into the legitimate supply chain which, due to holes in the law and regulatory structures, included a large cohort of unscrupulous licensed pharmaceutical wholesalers that sought to extract profits from the U.S. healthcare system but lacked a desire to engage in ethical, compliant transactions.[21]

As a result of this regulatory lapse, licensed pharmaceutical wholesalers engaged in criminal activity, serving to launder, place and legitimize medicine that had been adulterated, diverted, mislabeled, counterfeited, or improperly stored by criminals. Once unfit medicine was reintroduced into the legitimate supply chain, it could then be resold to one or multiple other purportedly legitimate trading partners and eventually dispensed or administered to patients. The corruptible nature of the national pharmaceutical distribution system led one perplexed Senator to declare what should have been obvious:

> "[t]he normal chain moves drugs from the manufacturer to a wholesaler to a pharmacy."[22]

The obvious implication is that permissiveness of non-normal behavior, like gray market wholesaler-to-wholesaler distribution schemes and gray market pharmacy-to-wholesaler distribution schemes, severely increases the risk to the pharmaceutical supply chain because those are the primary vectors for criminals to place and launder their counterfeit, adulterated and mislabeled drugs for profit.

The legislative record underlying the DSCSA is replete with evidence indicating that a "chain of custody" that tracks "exactly how our drug products travel through the often-complicated distribution system" is believed by Congress to be necessary to secure the U.S. pharmaceutical supply chain.

Recent Incidents of Adulteration, Misbranding, and Counterfeit Medicine Entering the Pharmaceutical Supply Chain Post-DSCSA

Despite the almost ten years that have passed since the enactment of the DSCSA, it is clear that the policy goals expressed by Congress in their floor statements have not been met, as adulteration, misbranding, diversion, and counterfeiting remain present in the U.S. pharmaceutical supply chain.

(1) In February 2022, the Wall Street Journal reported:

> "[A] ***network*** of little-known [***licensed***] ***drug*** . . . ***distributors*** sold illicit and potentially dangerous fake versions of [Gilead's] HIV medicines that ended up in pharmacies and in the hands of patients. In all, Gilead identified ***85,247 counterfeit bottles*** . . . ***over the past two years***. . . .

[20] *E.g.,* KATHERINE EBAN, DANGEROUS DOSES 89-94 (2005).
[21] *E.g., id.*
[22] 159 CONG. REC. S8025 (2013) (statement of Sen. Bennet).

> Gilead said it was aware of eight bottles with foreign tablets that SafeChain sold to pharmacies. One held an over-the-counter painkiller, another an HIV drug made by another company, three contained the antipsychotic drug Seroquel, and the remainder contained other Gilead drugs. ***One patient who unknowingly took Seroquel instead of their HIV pill 'could not speak or walk afterwards.'***" [23]

(2) In February 2022, the U.S. Department of Justice ("DOJ") reported the indictment of the owner and President of Woodfield Pharmaceutical LLC, a pharmaceutical repackager, relabeler, ***distributor, 3PL and reverse distributor*** in interstate commerce, for participation in a "conspiracy, trafficking in [promethazine-codeine] with a counterfeit market, and money laundering."[24] Importantly, the defendant had already been implicated in criminal pharmaceutical transactions, almost twenty years earlier, in the book *Dangerous Doses*.[25]

(3) In May 2022, the DOJ reported:

> "Dadaian [a New York physician] used his medical license – and allowed others to use it – to purchase expensive prescription drugs, primarily, cold-chain biologic infusion medications that typically are used to treat cancers, macular degeneration, and autoimmune diseases," which was then resold at a discount to two "individuals who ***owned and operated two businesses that were wholesale distributors of prescription drugs***," and who were attempting to circumvent the drug's restricted distribution scheme.[26]

(4) In August 2021, the DOJ announced the indictment of ***two pharmaceutical wholesaler [distributor]*** CEOs for:

> "purchas[ing] and distribut[ing] millions of dollars in diverted pharmaceuticals, . . . high priced medical drugs used to treat conditions such as mental illness, . . . [HIV], and cancer . . . acquired unlawfully -- through fraud, pharmacy burglaries, and cargo thefts, . . . in large quantities, at [ ] costs[s] well-below normal wholesale prices, and then introduc[ing] the diverted drugs back into the legitimate marketplace."[27]

---

[23] Joseph Walker & Corinne Ramey, *Drugmaker Gilead Alleges Counterfeiting Ring Sold its HIV Drugs*, Wall Street J., (Jan. 18, 2022) https://www.wsj.com/articles/drugmaker-gilead-alleges-counterfeiting-ring-sold-its-hiv-drugs-11642526471 (emphasis added).

[24] *Florida-Based Pharmaceutical President Indicted in Counterfeit Promethazine-Codeine Drug Trafficking Conspiracy*, U.S. ATTY'S. OFF., E.D.TX. (Feb. 2, 2022) https://www.justice.gov/usao-edtx/pr/florida-based-pharmaceutical-president-indicted-counterfeit-promethazine-codeine-drug.

[25] *See* KATHERINE EBAN, DANGEROUS DOSES 44-46, 73-74, 366, 371 (2005).

[26] *New York Doctor Admits Buying and Selling Oncology Medication for Profit*, U.S. DEP'T OF JUST. (May 16, 2022) https://www.justice.gov/usao-nj/pr/new-york-doctor-admits-buying-and-selling-oncology-medication-profit (emphasis added); *See generally* Information, United States v. Dadaian, No. 2:22-cr-00346-SDW (2022).

[27] *Two CEOs of Wholesale Pharmaceutical Companies and Two Owners of Bank Accounts Used for Money Laundering Indicted in Alleged Prescription Diversion Scheme*, U.S. ATT'YS. OFF., S.D.FL. (Oct. 18, 2019) https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/two-ceos-wholesale-pharmaceutical-companies-and-two-owners-bank-accounts-used-money-laundering.

Other Recent Criminal Activity in the U.S Pharmaceutical Supply Chain

(5) In May 2022, a New York City pharmacy received a letter purporting to be from the New York Office of Professional Discipline. The letter stated that the pharmacy had been referred to the office for "investigations of professional misconduct… includ[ing] participating in health care fraud; conspiring to bill Medicare and Medicaid…; [and] conspiring to pay kickbacks and bribes." The letter further went on to include that "an unannounced inspection of the premises and facilities will be made in order to insure [sic] the requirements of the law, rules and regulations are met." The following week, the criminals appeared at the pharmacy with fake badges, confiscated the pharmacy's medications, and drove away.[28]

(6) In July 2021, the New Hampshire Board of Pharmacy warned that "scam callers claiming to represent the New Hampshire Board of Pharmacy… ha[d] spoofed the Board's phone number…attempting to extort money or elicit sensitive information – e.g., license numbers, DEA registration numbers, etc."[29]

(7) In September 2021, Hercules was made aware of was a scam targeting Ohio pharmacies in which, "scammers pose as Board agents or representatives of a wholesaler and ask for information regarding the pharmacy's wholesale accounts . . .[with t]his information [ ] then being used to fraudulently order prescription medications."[30]

(8) In October 2021, Maine and other states were affected by a scam in which "scammers used "a spoof phone number that look[ed] like the Office of Professional and Occupational Regulation (OPOR) or the Department of Professional and Financial Regulation (DPFR) . . . contacting licensees in an effort to get licensees to share information, . . . telling the licensees that the licensing board or other regulator has opened an investigation and their license has been suspended or revoked . . . then ask[ing] the licensee to share or verify personal information over the phone."[31]

(9) In November 2021, the California Board of Pharmacy warned its licensees of a fraud attempt wherein a scammer called a pharmacy pretending to represent the board. The scammer represented to the pharmacy that there was a complaint against them and requested a wholesaler account number to investigate, with which the pharmacy complied. After business hours, the scammer placed an order for $90,000 worth of products with a wholesaler. The order was delivered and upon the delivery, the scammer called the pharmacy, this time posing as the wholesaler, claiming that the order was sent in error, and that they would send someone to pick it up.[32]

---

[28] *See infra,* Addendum II (copy of fraudulent letter provided by James R. Shiffer, Esq.).
[29] Email from customersupport@oplc.nh.gov, *Scam Phone Calls Claiming to be NH Board of Pharmacy* (Jul. 9, 2021) (on file with author).
[30] Email from State of Ohio Board of Pharmacy, *Scammers Posing as Board of Pharmacy or Wholesaler Staff* (Sept. 28, 2021) (on file with author).
[31] Email from Maine Board of Pharmacy, *Important Message on Scammers from the Maine Board of Pharmacy* (Oct. 19, 2021) (on file with author).
[32] Email from California State Board of Pharmacy, *Warning about New Scam Technique*, (Nov. 23, 2021) (on file with author).

(10) In June 2022 California again warned its licensees of scammers who "requested and obtained each pharmacy's DEA number and account purchasing information for their principal distributor . . . then called each distributor . . . and ordered between $100,000 and $300,000 worth of . . . HIV medications (Descovy, Triumeq, Odefsey) and Xarelto, Otezla, and Eliquis." The scammers would then arrange to pick up the diverted product.[33]

(11) Colorado warned of the same ordering and recall scam across the country, wherein scammers would pose as a pharmacy and place an order with a wholesaler. Upon shipment, the scammer would pose as the wholesaler, claim the order was shipped in error, and request the shipment be returned via a courier who would arrive to the pharmacy.[34]

(12) The Ohio Board of Pharmacy warned of a slightly different scam compared to California and Colorado, as scammers acting within Ohio were posing as agents of the Ohio Board of Pharmacy and would "ask to verify [licensees'] terminal distributor of dangerous drugs (TDDD) license[s] and DEA registration[s]," in order to complete the order and recall scam.[35]

This recently reported criminal behavior is likely a fraction of the actual number of criminal endeavors in the pharmaceutical supply chain.[36]

Clearly, the DSCSA, as implemented to date, has not put these issues in the past. In a write-up of the Gilead case, where ***85,247 counterfeit bottles*** of HIV prophylaxis were dispensed, the Wall Street Journal credited the Lanham Act, an intellectual property statute, rather than the DSCSA, for Gilead's ability to remove counterfeited medications from the supply chain, implying that the DSCSA, in its current state, is ineffective to secure the pharmaceutical supply chain.

> "***A 2013 law*** required sellers of prescription drugs to provide buyers with a transaction history document known as a pedigree, which details each previous seller and buyer in the supply chain. The law *was* ***an effort*** to crack down on the practice of diverting medicines from the regulated supply chain and then reselling them to pharmacies at discounted prices using falsified pedigrees."[37]

[33] Email from California State Board of Pharmacy, *FRAUD ALERT: Scammers Diverting Drug Shipments from Distributors, Pharmacies*, (June 24, 2022) (on file with author).
[34] Email from Colorado Department of Regulatory Agencies Division of Professions and Occupations, *Fraud Alert: Increase in Product Ordering and Recall Fraud Incidents*, (May 13, 2022) (on file with author).
[35] Email from State of Ohio Board of Pharmacy, *Terminal Distributor and Wholesaler Scam Alert*, (June 16, 2022) (on file with author).
[36] The pharmaceutical industry and specifically pharmacies have recently fallen victim to three types of phishing scams, commonly referred to as (i) product recall fraud; (ii) pharmacy/wholesaler fraud; and (iii) bank account/payment fraud. National Association of Boards of Pharmacy, *Beware of Three Unique Phishing Scams Impacting Pharmacy* (Jan. 4, 2022) https://nabp.pharmacy/news/blog/regulatory_news/beware-of-three-unique-phishing-scams-impacting-pharmacy.
[37] Walker & Ramey, *supra* note 23 (emphasis added). *See also* Second Amended Compl., Gilead Sciences, Inc., v. Safe Chain Solutions, LLC, et al., No. 21-cv-4106 (AMD) (RER) (2021) (ECF No. 147).

This sentiment was echoed in a recent article entitled "*While a Law Designed to Thwart Counterfeit Medicines Lurches Into Full Force, Fake Pills Keep Circulating*."[38]

How many people contracted HIV due to this malfeasance? Given the clear legislative intent which motivated the DSCSA, why is the DSCSA not working to secure the supply chain?

Deviations between the Legislative Intent of the DSCSA and its Written Text

In large part, these supply chain issues persist because of critical features in the DSCSA having been shrewdly crafted in diametric opposition to the expressly stated and unmistakably implied legislative intent underlying the statute.

The legislative intent of the DSCSA includes:

> (1) Creating a "comprehensive, electronic, interoperable framework" that establishes a "chain of custody"[39] and "tracks each package of drugs at the unit level"[40] so that industry and regulators "know exactly how our drug products travel through the often-complicated distribution system"[41] and so "[pharmacists can] determine with any certainty where a drug has been;"[42]
>
> (2) "Rais[ing] the bar for wholesale distributors"[43] and promoting the utilization "[t]he normal [supply] chain [which] moves drugs from the manufacturer to a wholesaler to a pharmacy;"[44]
>
> (3) Effectuating these legislative public policy goals robustly, as "one of the basic functions of government [is] making sure that markets work by ensuring that no one cuts corners that the customer can't see or that put someone's family at risk;"[45]
>
> (4) Achieving these goals such that our nation will "have full confidence that the medication is as prescribed and that no counterfeit or adulterated drug has entered the supply chain."[46]

[38] Ed Silverman & Jonathan Wosen, *While a Law Designed to Thwart Counterfeit Medicines Lurches Into Full Force, Fake Pills Keep Circulating,* STAT (May 31, 2022).
[39] 159 CONG. REC. S8074 (2013) (statement of Sen. Feinstein).
[40] 159 CONG. REC. H5961 (2013) (statement of Rep. Waxman).
[41] 159 CONG. REC. S8075 (2013) (statement of Sen. Harkin).
[42] 159 CONG. REC. S8025 (2013) (statement of Sen. Bennet).
[43] *Id*. at S8024.
[44] *Id.*
[45] 159 CONG. REC. S8075 (2013) (statement of Sen. Warren).
[46] 159 CONG. REC. H5962 (2013) (statement of Rep. Latta).

In contradiction to this clear legislative intent, the DSCSA is crafted to ensure that:

i. Critical track-and-trace information evidencing and documenting prior ownership is legally required to be removed from the T3/pedigree

Critical track-and-trace information evidencing and documenting prior ownership is legally required to be removed and laundered from the T3/pedigree; ***the DSCSA instructs ATPs to engage in data laundering***.

Under the DSCSA, a wholesale distributor who wishes to accept returned pharmaceuticals must be able to "associate [the] returned product with the transaction information and transaction statement associated with that product."[47] Prior to reselling that product, the wholesaler must verify the product identifier of each sealed homogeneous case or package of returned drugs against the associated paperwork.[48] Yet 21 U.S.C. § 360eee-1(c)(1)(B)(i)(II), obligates that "[f]or all transactions after [a wholesale distributor accepts a saleable return], the transaction history, as applicable, of such product, ***shall begin*** with the wholesale distributor that accepted and verified the returned product."[49]

Where a wholesale distributor sells a pharmaceutical to a dispenser who subsequently returns it, that drug is at heightened risk of adulteration, exposure to environmental excursions, fraud, and other forms of misconduct that affect safety and reliability.[50] In result, § 360eee-1(c)(1)(B)(i)(II), ***forces wholesale distributors to exclude from T3 Information the entire prior history of a returned drug's travel through the supply chain*** and ***obligates them to launder data*** of a drug's Transaction History ("TH") in a saleable-returns use case, precisely where that drug is subject to heightened risk and would benefit from a robust, complete TH.

Evidencing prior ownership is squarely within the legislative intent of the DSCSA and robust THs empower healthcare providers with information upon which they can make informed purchasing and prescribing choices. Under the current saleable returns paradigm, however, a product sold, shipped in 110° weather, returned in 110° weather, resold, reshipped in 110° weather, re-returned in 110° weather, only to be sold again, would have the very same TH as a product that traveled one time through the normal supply chain, downstream from manufacturer to wholesaler to pharmacy.

The risk, and thus the economic cost, of returns should be fairly placed with the least cost avoiders such as the prior purchaser or the wholesale distributors, who wield substantial control over the distribution schemes for American medicines. The fact that a drug may sell for less if a downstream customer is aware of its history of prior returns does not justify shrouding its TH from American pharmacies; such risks and costs should not burden downstream bona fide purchasers in good faith, nor should they be inflicted at the expense of the quality of the national pharmaceutical supply nor the system of DSCSA & FD&C Act compliance. Under the current system, information essential to

[47] 21 U.S.C. § 360eee-1(c)(1)(B)(i)(II).
[48] 21 U.S.C. § 360eee-1(c)(4)(D).
[49] (emphasis added).
[50] "Pharmacists cannot determine with any certainty where a drug has been and whether it has been secured and safely stored on its way to a pharmacy . . . The more times a drug goes back and forth and changes hands, the more opportunities criminals find to enter the system." 159 CONG. REC. S8025 (2013) (statement of Sen. Bennet). "At any time in the delivery process, there is opportunity for counterfeit drugs to enter the supply chain or real drugs to be diverted for illegitimate uses. In 2009, for example, 129,000 vials of insulin were stolen. These vials later reappeared and were sold to pharmacies and hospitals. We do not know who was handling these vials after they were stolen, or if they were stored under appropriate conditions." 159 CONG. REC. S8074 (2013) (statement of Sen. Feinstein).

healthcare professionals is withheld from them, precisely in the use cases where additional risk inheres in the supply chain. This vastly increases the supply chain risk borne by pharmacies, hospitals, clinics, and ultimately patients.

Obligating the ***laundering*** of prior ownership information under the moniker of "saleable returns" facilitates a pharmaceutical supply chain scheme analogous to the financial crime of ***churning. Churning***, in the context of financial services, is the practice of executing unnecessary trades for an investment account by a salesperson or broker in order to generate excess commissions, unwarranted by any increased earnings. ***Churning***, as analogized to the pharmaceutical supply chain, takes the form of double chargebacks or negative chargebacks on pricing discounts to wholesalers and third parties and service fees paid to wholesalers. This practice functions as a private and hidden tax that manufacturers inevitably pass onto pharmacies, healthcare providers, and payors across all their medicines. Given the social urgency of decreasing the cost of prescription medicine, churning multiple chargebacks is an unacceptable business practice, contributing to the potentially deadly consequences of unduly high drug costs.[51] This unnecessary cost inflation can be prevented in part by repealing the legal obligation under 21 U.S.C. § 360eee-1(c)(1)(B)(i)(II) to launder prior ownership information under the "saleable returns" moniker therein.

Saleable returns*,* as addressed in § 360eee-1(c)(1)(B)(i)(II), does not "raise the bar for wholesale distributors," as the DSCSA intended. Prohibiting the communication of the fact of prior ownership is not only contrary to the obvious legislative intent underpinning the DSCSA, but it also obscures the prior ownership of medications, increases risks to patients, and creates the opacity needed for these endemic gray market supply chain schemes.

ii. Wholesalers are legally prohibited from communicating their compliance information upstream to manufacturers

Anomalously, the DSCSA has a compliance gag order.

Manufacturers seeking to audit supply chain compliance or audit for churning or investigate criminal adulteration and counterfeiting may not rely on ethical and willing wholesale distributors, as wholesalers are prohibited by law from communicating their compliance information to manufacturers under the combined effect of several provisions in the DSCSA.

The first provision is found in the "Product Tracing" subsection of the "Wholesale Distributor Requirements" at 21 U.S.C. § 360eee-1(c)(1)(A)(v)(II). It reads, "A wholesale distributor shall . . . maintain the confidentiality of the transaction information (including any lot level information consistent with the requirements of this section), transaction history, and transaction statement for a product in a manner that prohibits disclosure to any person other than the Secretary or other appropriate Federal or State official, except to comply with clauses (ii) [an exception for downstream purchases in normal-risk distribution chains] and (iii) [an exception for downstream purchases in high-risk, abnormal distribution chains], and, as applicable, pursuant to an agreement under subparagraph (D)."[52]

[51] Mackenzie Bean, *Many Medicare Patients Don't Fill Prescriptions for Specialty Drugs, Study Finds*, BECKER'S HOSP. REV. (Apr. 7, 2022) https://www.beckershospitalreview.com/pharmacy/many-medicare-patients-don-t-fill-prescriptions-for-specialty-drugs-study-finds.html#:~:text=Philanthropy-,Many%20Medicare%20patients%20don't%20fill,for%20specialty%20drugs%2C%20study%20finds&text=Many%20Medicare%20beneficiaries%20who%20don,published%20in%20Health%20Affairs%20found; *Hamel* et al., *Public Opinion on Prescription Drugs and Their Prices*, KAISER FAMILY FOUND. (Apr. 5, 2022) https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices.

[52] 21 U.S.C. § 360eee-1(c)(1)(A)(v)(II).

There are three exceptions to this provision, referred to as the "(ii), (iii), and (D) exceptions." (ii) and (iii) exceptions permit wholesale distributors to transmit T3 Information to downstream members of the supply chain in order to comply with the applicable product tracing requirements, depending on the category of supplier purchased from.[53] The (D) exception permits a wholesaler to disclose T3 Information to a downstream member of the supply chain if permitted to under a written "trading partner agreement" between that subsequent purchaser and the selling wholesaler.[54] The (D) exception facilitates a provision located in the "Dispenser Requirements" section at 21 U.S.C. § 360eee-1(d)(1)(B), which permits dispensers to enter into written agreements with third parties, such as wholesalers, under which the third party will maintain the T3 Information that dispenser would otherwise be required to maintain,[55] though the language of the subparagraph (D) does not limit its applicability to this specific business arrangement.

The second relevant provision is found in paragraph (g) interoperable system requirements which become effective on November 27, 2023, at 21 U.S.C. § 360eee-1(g)(1)(E)(ii). This provision states, "On the date that is 10 years after November 27, 2013, the following interoperable, electronic tracing of product at the package level requirements shall go into effect: (E)The systems and processes necessary to promptly facilitate gathering the information necessary to produce the transaction information for each transaction going back to the manufacturer, as applicable, shall be required . . . in the event of a request by an authorized trading partner, in a secure manner that ensures the protection of confidential commercial information and trade secrets, for purposes of investigating a suspect product or assisting the Secretary (or other appropriate Federal or State official) with a request described in clause (i).[56]

Importantly, the phrase "confidential commercial information and trade secrets" is not defined either in the text of the DSCSA or in any other provision of the FD&C Act. However, in the context of the DSCSA's regulatory scheme, the only reasonable interpretation is that it extends the requirements of the prior confidentiality provision, which though presently effective, only binds wholesalers, to all ATPs upon the effective date of the 2023 interoperable requirements, and thereby at least prohibits the dissemination of downstream T3 Information to upstream suppliers of drugs in § 360eee-1(c)(1)(A)(v)(II). There is no competing definition of the phrase "confidential commercial information and trade secrets," nor any provision providing a competing definition of what it would mean to "ensure[ ] the protection" of the same in the DSCSA or the FD&C Act broadly. In two other locations where the DSCSA refers to confidentiality obligations, it refers to them in the context of T3 Information.[57] Additionally, the context of the

[53] 21 U.S.C. § 360eee-1(c)(1)(A)(ii–iii).
[54] "[A] wholesale distributor may disclose the transaction information . . . , transaction history, or transaction statement of a product to the subsequent purchaser of the product, pursuant to a written agreement between such wholesale distributor and such subsequent purchaser. Nothing in this subparagraph shall be construed to limit the applicability of subparagraphs (A) through (C)." 21 U.S.C. § 360eee-1(c)(1)(D).
[55] "(B)Agreements with third parties . . . A dispenser may enter into a written agreement with a third party, including an authorized wholesale distributor, under which the third party confidentially maintains the transaction information, transaction history, and transaction statements required to be maintained under this subsection on behalf of the dispenser. If a dispenser enters into such an agreement, the dispenser shall maintain a copy of the written agreement and shall not be relieved of the obligations of the dispenser under this subsection." 21 U.S.C. § 360eee-1(d)(1)(B).
[56] 21 U.S.C. § 360eee-1(g)(1)(E)(ii) (emphasis added).
[57] 21 U.S.C. § 360eee-1(c)(1)(A)(v)(II) ("A wholesale distributor shall . . . maintain the confidentiality of the transaction information . . . , transaction history, and transaction statement for a product in a manner that prohibits disclosure to any person other than the Secretary or other appropriate Federal or State official, except to comply with clauses (ii) and (iii), and as applicable, pursuant to an agreement under subparagraph (D)."); 21 U.S.C. § 360eee-1(d)(1)(B) ("A dispenser may enter into a written agreement with a third party, including an authorized wholesale distributor, under which the third party confidentially maintains the transaction information, transaction history, and transaction statements required to be maintained under this subsection on behalf of the dispenser.").

2023 confidentiality provision is the dissemination of TI.[58] Finally, besides notifications and investigation assistance, the only information which the DSCSA expressly contemplates that ATPs must exchange is T3 Information. This is confirmed by administrative materials released by the FDA. A draft guidance document released in June 2021 stated,

> "Section 582(h)(3)(A)(iii) of the FD&C Act states that FDA's guidance on attributes of the enhanced system must ensure the protection of confidential commercial information and trade secrets. **Trading partners should use individual system(s) and procedures that protect confidential commercial information and trade secrets. FDA expects trading partners to ensure that they will maintain the confidentiality of product tracing information** through usual business practices. FDA will treat any information provided to the Agency like other information submitted to us by industry or stakeholders, including complying with requirements under the Freedom of Information Act and regulations prohibiting public disclosure of confidential commercial information and trade secrets."[59]

A second guidance document released in July 2022, recommitted ATPs to protecting confidential commercial information, in the context of tracing provisions of the DSCSA. In its recommendation on how trading partners should build technological solutions for DSCSA compliance, the FDA stated that any approach used by trading partners should be one that utilizes data standards that, "ensure the protection of confidential commercial information and trade secrets." [60]

When read as a whole, and in light of the FDA's interpretation, these confidentiality provisions operate to (i) presently prohibit WDs from disseminating T3 Information in their possession to anyone except a downstream purchaser in privity or with whom it has a written agreement information maintenance agreement with, and (ii) to extend this same prohibition to all ATPs in 2023.

In the case of the normative supply chain arrangement, wherein a manufacturer sells a product to a wholesale distributor who distributes it to one or more dispensers, this prevents manufacturers from receiving any information regarding the distribution of their products after they have been introduced into the supply chain. The DSCSA does not provide for the reverse flow of information in the supply chain except in the case of returns.[61] Wholesale distributors, which often link manufacturers and dispensers, are uniquely placed in the supply chain to know the circumstances of both the entry of a drug into the chain and its terminal distribution to a dispenser. Thus, but for the above confidentiality provisions, a wholesale distributor would often be able to perform an end-to-end trace of a drug

---

[58] 21 U.S.C. § 360eee-1(g)(1)(E)(ii) ("The systems and processes necessary to promptly facilitate gathering the information necessary to produce the transaction information for each transaction going back to the manufacturer, as applicable, shall be required . . . in the event of a request by an authorized trading partner, in a secure manner that ensures the protection of confidential commercial information and trade secrets, for purposes of investigating a suspect product or assisting the Secretary (or other appropriate Federal or State official) with a request described in clause (i).") (emphasis added).

[59] U.S. FOOD & DRUG ADMIN., ENHANCED DRUG DISTRIBUTION SECURITY AT THE PACKAGE LEVEL UNDER THE DRUG SUPPLY CHAIN SECURITY ACT, GUIDANCE FOR INDUSTRY 7 (2021) https://www.fda.gov/media/149704/download (draft guidance).

[60] U.S. FOOD & DRUG ADMIN., DSCSA STANDARDS FOR THE INTEROPERABLE EXCHANGE OF INFORMATION FOR TRACING OF CERTAIN HUMAN, FINISHED, PRESCRIPTION DRUGS, GUIDANCE FOR INDUSTRY §§ II & IX (2022) https://www.fda.gov/media/90548/download (draft guidance).

[61] The aforementioned ongoing E.D.N.Y. *Gilead Sciences, Inc. v. Safe Chain Solutions, LLC,* case makes evident the extraordinary lengths manufacturers must go to in order to combat illicit trafficking related to their products, including utilizing private investigators to personally visit the offices and warehouses of alleged counterfeiters and conduct civil seizures. *See supra* note 37, at 28–29, 39–42, 44, 56–57. Even after doing so, Gilead was unable to locate several defendants who participated in the counterfeiting conspiracy. *Id.* at 63.

on behalf of a manufacturer, payor, or benefit manager, informing that supplier of the entire path a drug has taken through the supply chain and many other crucial details. Wholesalers are legally prohibited from communicating information to manufacturer-suppliers and end-chain entities that would enable them to conduct a meaningful audit, investigations of drug diversion, fraud, counterfeiting, theft, adulteration, and improper storage conditions or scrutinize the distribution chain products bearing their trademarks travel. This not only impacts the interests of manufacturers but also of wholesale distributors, and soon all ATPs, who may wish to voluntarily utilize the information they possess, own, and control, in order to contribute to the safety of the supply chain they all participate in as members and patients.

iii. Known and risky market behaviors, with no legitimate economic or market rationale, remain functional as crime vectors, devoid of regulatory prohibitions

> "[The DSCSA] ***raises the bar for wholesale distributors*** . . . ***The normal chain moves drugs from the manufacturer to a wholesaler to a pharmacy***. …"[62]

Wholesaler-to-wholesaler trade is known in industry, referred to by court filings and legislative reports as "the gray market." Permissiveness of gray market behavior is the modality by which criminals trafficking illegitimate pharmaceuticals access the legitimate pharmaceutical supply chain.

Despite a stated legislative intent disfavoring lateral distribution of pharmaceuticals and noting the increased supply chain risk inherent in such transactions, the DSCSA contradicts its creators' intent and is permissive of gray market, horizontal trade, as evidenced by its bifurcation of track-and-trace obligations between the normal distribution chain and the lateral market.[63]

Specifically, the DSCSA distinguishes between transactions in which a wholesaler purchased from a manufacturer, ***exclusive distributor of the manufacturer,*** or repackager in privity with the manufacturer from transactions wherein a wholesaler purchased a product from anyone else, namely wholesalers and repackagers not in privity with the manufacturer (i.e. secondary distributors) and primary ***non-exclusive distributors of the manufacturer.*** [64] Transactions of the prior category, representing the less-risky model, are required to transmit THs downstream which indicate every upstream transaction. ***For transactions in the latter category, the risker distribution model, wholesalers are required to truncate certain upstream transactions***, often the first manufacturer-wholesaler transaction.[65]

The FDA should ban ***all*** wholesaler-to-wholesaler transactions.

While wholesaler-to-wholesaler transactions with an ***exclusive distributor*** of the manufacturer approach legitimacy, these transactions should be prohibited as there are other mechanisms available such as third-party logistics services. ***Wholesaler-to-wholesaler transactions are the entrance ramps for criminals licensed as Authorized Trading Partners[66] to place adulterated and counterfeit medicine into our supply chain***.

Again, note the experience of drug manufacturer Gilead with counterfeiting of its HIV/AIDS medicine:

---

[62] 159 CONG. REC. S8025 (2013) (statement of Sen. Bennet).
[63] 21 U.S.C. § 360eee-1(c)(1)(A)(ii–iv).
[64] *Id.*
[65] *See* 21 U.S.C. § 360eee-1(c)(1)(A)(iv).
[66] *See* 21 U.S.C. § 360eee(2).

> "[A] network of little-known [***Licensed***] ***drug … distributors*** sold illicit and potentially dangerous fake versions of its HIV medicines that ended up in pharmacies and in the hands of patients. In all, Gilead identified ***85,247 counterfeit bottles*** … ***over the past two years*** … [and where] ***One patient who unknowingly took Seroquel instead of their HIV pill "could not speak or walk afterwards***."[67]

These counterfeit medicines reached the patient via a perennial daisy-chain of licensed wholesaler-to-licensed wholesaler-transactions. This is even documented in the declaration on the website of one of the "***non-exclusive***" wholesalers, SafeChain, alleged to have participated in the propagation of the counterfeit Gilead medicines:

> "***[W]e partner with . . . wholesalers.***"[68]

In another account of this counterfeiting scheme, the owners of SafeChain described themselves as "unwitting participant[s]" in a counterfeiting scheme they believed to have taken place "way upstream" in the supply chain.[69] Assuming this assertion as true, the supply chain failure here must be attributed to regulatory choices, specifically the permissive allowance of wholesaler-to-wholesaler transactions, a type of supply chain conduct which inherently increases the risk of supply chain exposure to gray and black markets.

Assuming as true the company's assertion that it "never knowingly sold anything that would be considered counterfeit,"[70] it is still the case that SafeChain ***knowingly*** engaged in the business of secondary drug distribution, a practice which, though proven to be harmful and deadly to patients, is legal in the current permissive regulatory climate.[71] It is perplexing that the risk-laden behavior which SafeChain allegedly engaged in - the sourcing pharmaceuticals from non-manufacturer supply chain entities - has not been prohibited.

Allowing ***any*** wholesaler-to-wholesaler transactions constitutes the ***placement vehicle for criminals'*** stolen, counterfeit, misbranded or adulterated medicines. Allowing "non-exclusive" wholesaler-to-wholesaler transactions is the pharmaceutical super-highway for criminals to do the same.[72]

iv. The "Five Percent Rule" is concurrently dangerous and fosters unlicensed wholesale distribution.

FDA proposes to codify the "five percent rule" by defining the term, "minimal quantities," as used in the DSCSA, thereby allowing retail pharmacies to participate in the trade in prescription drugs to licensed practitioners without obtaining a wholesale distributor license.[73]

The FDA acknowledges that the diversion of products is inherent in the very meaning of unlicensed wholesale

---

[67] Walker & Ramey, *supra* note 23 (emphasis added).
[68] *See* www.safechain.com (visited Jan. 2022).
[69] *Supra* note 38.
[70] *Id.*
[71] *E.g.* Staff Rep., Sen. Rockefeller, Sen. Harkin, & Rep. Cummings, *Shining Light on the "Gray Market": An Examination of Why Hospitals are Forced to Pay Exorbitant Prices for Prescription Drugs Facing Critical Shortages* 5–6 n. 28, 9–10, 16–17, 26–27 (July 25, 2012) https://oversight.house.gov/sites/democrats.oversight.house.gov/files/migrated/uploads/7.25.12%20Staff%20Report%20Shining%20Light%20on%20the%20Gray%20Market.pdf.
[72] *See* Addendum I.
[73] Proposed Standards § 205.3(h).

distribution.[74] "Retail pharmacies" are calibrated to dispense medicine to patients and manage the medication therapy they receive; pharmacy regulations and regulators, likewise focus on pharmacy-to-patient charges and not the task of pharmaceutical supply chain compliance. Allowing pharmacies to trade in prescription drugs seriously increases the risk of diverted, adulterated and counterfeit medicine entering the legitimate supply chain. Additionally, as this supply chain risk increases due to the conduct of pharmacies acting as distributors, the "five precent rule" paradoxically excludes such actors from compliance obligations for trade under the DSCSA and FD&C Act, placing such transactions outside of the regulated bounds of the pharmaceutical supply chain.

Should the FDA believe itself committed to the risk-enhanced paradigm embodied in the five percent rule, ***Hercules recommends that this trade behavior be limited to pharmacies with advanced specialty pharmacy accreditations***. As such, FDA should require that retail pharmacies operating under the five-percent rule maintain advanced accreditation issued by at least one of the following: the National Association of Boards of Pharmacy (NABP), the Accreditation Commission for Health Care (ACHC), or the Utilization Review Accreditation Commission (URAC).[75] Advanced accreditation programs prevent adulterated, diverted, and counterfeit drugs from entering the pharmaceutical supply chain by ensuring "that accredited facilities operate legitimately, are licensed in good standing, and are employing and displaying quality practices for safely storing, handling, and shipping prescription drugs and devices." Through careful review of application documentation, policies and procedures, drug sources, and detailed on-site surveys of distribution facilities, accreditation programs deter threats to the supply chain and safeguard the integrity of the medications that are dispensed to patients. As it is unmoored from core responsibilities associated with trade in pharmaceuticals, pharmacy distribution under the "five percent rule" needs, at a minimum, an accreditation body ensuring the safety of the pharmaceutical supply chain.

v. The true nature and identity of wholesale distributers is consolidated

FDA estimates that 1,951 wholesalers will become subject to the proposed regulations.[76] In light of the extraordinary consolidation of at least 95% of the distribution market amongst three companies,[77] and in light of the non-wholesaler trading partners who acquire wholesaler licensure in order to meet internal logistics needs, such as hospital systems and pharmacy chains operating a central ship-to distribution center, it is clear that the number of actual and distinct commercial wholesaler distributors is far less. Less than 500 out of the 30,000+ reported wholesale WD and 3PL licenses listed in the FDA's Wholesale Distributor and Third-Party Logistics Provider Reporting Database, are wholesalers of pharmaceutical products, with more than 150 of those 500 being subsidiaries of another licensed

[74] "This proposed rule, when finalized, codifies the principle that the five percent rule only applies to pharmacy sales for office use. Sales above five percent for office use, or any sales to a wholesale distributor, require the pharmacy to become licensed and regulated as a wholesale distributor. This Proposed Standards will clarify this requirement and close a potential loophole that could lead to diversion of products and excessive sales from dispensers who are not licensed and registered as wholesale distributors when they are engaging in wholesale distribution." Proposed Standards at 6711-12.

[75] *See Pharmacy Accreditations*, NAT'L ASS'N OF BDS. OF PHARM., https://nabp.pharmacy/programs/accreditations-inspections/#pharmacy (last visited Aug. 22, 2022); *Pharmacy Accreditation*, ACHC, https://www.achc.org/pharmacy (last visited Aug. 22, 2022); *Pharmacy Accreditations & Certifications*, urac, https://www.urac.org/accreditations-certifications/programs/pharmacy-accreditations-certifications-suite (last visited Aug. 22, 2022).

[76] "Consistent with our PRIA, we estimate that 459 3PL facilities and 1,951 WDDs will become subject to the reporting requirements." Proposed Standards at 6735.

[77] *E.g.,* Adam J. Fein, Ph.D., *Six Crucial Trends Facing U.S. Drug Wholesalers,* DRUG CHANNELS (Dec. 1, 2020) https://www.drugchannels.net/2020/12/six-crucial-trends-facing-us-drug.html ("These wholesalers' combined share of the channel has grown in recent years, from 87% in 2012 to 95% in 2019."); Adam J. Fein, Ph.D. *The Big Three Wholesalers: Revenues and Channel Share Up, Profits Down,* Drug Channels (Oct. 2, 2019). https://www.drugchannels.net/2019/10/the-big-three-wholesalers-revenues-and.html.

wholesaler. Smaller secondary wholesalers that engage in wholesaler-to-wholesaler drug transactions must also be recognized as contributing to the consolidation of primary distributors in the United States. Large wholesalers, upstream, often unload churned and returned inventory to gray market, secondary distributors and the DSCA, as written, guarantees opacity by requiring "data laundering," by the "compliance gag order," and by being permissive of gray market transactions. Clearly, wholesale distribution in the pharmaceutical supply chain is dangerously and exploitatively consolidated, and the levels of market and consumer benefitting competition are harmfully low.[78]

Licensure for all wholesaler applications should acknowledge ownership in the identity of the applicant

In the FDA's present proposed regulations, the general application requirements[79] and reporting requirements[80] are distinguished by business entity type. FDA's Proposed Standards do not require corporations and limited liability companies to include ownership information in a wholesaler license application. The Proposed Standards include reporting requirements triggered based on the FDA's definition of a "change of entity ownership," which is further bifurcated based on business organization type.[81] The "change of entity ownership" definition in the Proposed Standards *excludes* stock transfers for Limited Liability Companies and Corporation,[82] thereby precluding these events from triggering reporting requirements.

A wholesale distributor's ownership is the core of its identity, a fact evidenced by the Proposed Standards requirement that "[a]ny change in the person engaged in wholesale distribution will require a new license prior to beginning operations."[83] National licensure standards for wholesalers should require all applicants and license holders to identify themselves through its ownership.

In the case of corporations, transfers of privately held stock are not subject to the same federal recordkeeping mandates as companies traded on major stock indices. The FDA should thus require all licensed wholesaler businesses to report changes of ownership over a certain percentage threshold, such as 10%, but exempting publicly-traded companies listed on a major stock index.

The authority under which a wholesaler may continue to operate, post-expiration of their wholesaler license

The DSCSA restricts interstate commerce in pharmaceuticals to ATPs. Allowing continued operations during licensure renewal and processing is critical to avoid massive disruptions in the supply chain. Under the Proposed Standards, (i) a license remains valid until the date of expiration (unless suspended or revoked);[84] (ii) if there are

[78] *Comment to the Fed. Trade Commn's Req. for Information on Merger Enforcement*, ASSN. FOR ACCESSIBLE MEDICINES, Docket ID: FTC-2022-0003-0001, (March 2022); *see also* David Wainer, *Failing in an Oligopoly Takes Serious Mismanagement,* WALL. STREET. JOURN. (Aug. 22, 2022) ("America's drug distribution industry[] [is] dominated by an oligarchy of three companies.") https://www.wsj.com/articles/failing-in-an-oligopoly-takes-serious-mismanagement-11661041126.
[79] Proposed Standards § 205.22(c).
[80] Proposed Standards §205.24.
[81] Proposed Standards § 205.23(b).
[82] Proposed Standards §§ 205.3(b)(3–4).
[83] Proposed Standards § 205.24(c).
[84] Proposed Standards § 205.23(e).

administrative delays in processing license renewals, a wholesaler may continue to operate past its license expiration date;[85] and (iii) a wholesaler license is effective on the date the license certificate is *issued*.[86]

Consequently, there will be a period of time—between the expiration of the prior license and the effectivity of the newly issued license—where a wholesaler may operate without an authorizing license. The effective date of a renewed license should immediately succeed the expiration date of the prior license, to avoid gaps in authorized trading partner status.

Requiring the Protection of Trade Secrets via Restrictive Covenants between Approved Organizations and their Employees and Contractors

The FDA's proposed general qualifications of approved organizations mitigate conflicts of interests amongst approved organizations and their employees and subcontractors.[87] For example, approved organizations *and* their employees are prohibited from engaging in prescription drug-related activities, or from being affiliated with any trading partner. Further, approved organizations and their employees are required to enter into a written agreement with each applicant before the applicant's confidential and proprietary information is disclosed to the approved organization.

By operation of law, AO's and their employees and contractors will have access to trade secrets and proprietary know-how possessed by the wholesale distributors and 3PLs they regulate.

The Proposed Standards should further (i) require employees of approved organizations to be subject to non-compete restrictions which restrict employment with other AO's, licensed wholesale distributors and 3PLs for eighteen months after the termination of employment; and (ii) require serious non-disclosure agreements of AO's and their employees.

The FDA should take a strong stand to ensure that the licensure process and the involvement of AOs is not be used as a means to circumvent trade secrets laws.

Federalism

Hercules notes the DSCSA's novel approach, which (i) preempts state regulatory authority;[88] (ii) privatizes that preempted authority; (iii) deputizes third parties to exercise that authority;[89] and provides for (iv) adjudications of all denials, suspensions, or revocations of 3PL and wholesale distributor licenses in FDA administrative courts.[90]

---

[85] "A license will be considered valid during any period of the administrative delay on the part of the licensing authority, if the wholesale distributor timely submitted the renewal application." Proposed Standards § 205.20(b).
[86] Proposed Standards § 205.23(d).
[87] Proposed Standards 205.32(a).
[88] "As discussed in section X (Federalism), section 585(b)(1) of the FD&C Act (21 U.S.C. 360eee-4(b)(1)) preempts States and localities from establishing or continuing requirements for 3PL or WDD licensure that are different from the national standards and requirements applicable under sections 584 and 503(e) of the FD&C Act." *Supra* note 9, at 6709.
[89] "[T]his Proposed Standards will also set forth the standards applicable to, and the requirements for approval of, third-party organizations involved in the licensure and inspection process ('approved organizations' or 'AOs')." *Id.*
[90] "[T]he regulation proposes that wholesale distributors and 3PLs could request a formal evidentiary public hearing under part 12 for review of decisions affecting the denial, suspension, or revocation of 3PL or wholesale distributor licenses issued by the

As the pharmaceutical supply chain relies on both strong federal leadership and robust State participation, Hercules hopes that the FDA's efforts to make the pharmaceutical supply chain safe will leverage both federal and state authorities, rather than merely centralizing power at the national level and failing to use it to safeguard the U.S. public.

We also hope that the proposed system does not infringe on the fundamental 10th Amendment constitutional guardrails articulated by Justice Sandra Day O'Connor in *New York v. United States*:

> "As an initial matter, Congress may not simply 'commandee[r] the legislative processes of the States by directly compelling them to enact and enforce a federal regulatory program.' . . .
>
> While Congress has substantial powers to govern the Nation directly, including in areas of intimate concern to the States, the Constitution has never been understood to confer upon Congress the ability to require the States to govern according to Congress' instructions."[91]

Not only do the collective States retain sovereign powers "reserved to the States respectively,"[92] but they are also held politically accountable by their citizenry, to whom they are closer. It is state legislatures and executive officials whose voters suffer when compliance misconduct in the pharmaceutical supply chain is left unchecked, and whose tenures and budgets are most at stake. They should remain active participants in the regulation of this sector of industry.[93]

Presumably if a wholesaler intentionally obstructed government administration, falsified business documents, or committed fraud or another serious act of moral turpitude, a State would retain its police power to revoke that entity's state wholesale license and bar that entity from the benefits of participating in the marketplace offered by its state.[94]

Conclusion

The placement of counterfeit, adulterated, mislabeled, and stolen medicine into the pharmaceutical supply chain necessarily involves the participation of authorized trading partners, and in the vast preponderance of these cases licensed wholesale distributors are involved.

Given the astonishingly poor supply chain wide record on compliance and the implication of wholesale distributors in gray market schemes (i.e. counterfeiting, adulteration, and mislabeling) and the sector's contribution to the rampant

---

Secretary of Health and Human Services (Secretary), sections 503(e), 583, and 584 of the FD&C Act would be added to the list of statutory sections under which there is the opportunity for a hearing under §§ 10.50(c) and 12.21(a)(2), regarding such decisions" *Id.* at 6710.

[91] 505 U.S. 144, 161-62 (1992).

[92] U.S. CONST., amend. X ("The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.).

[93] The Centers for Disease Control estimates State-Level Economic Costs of Opioid Use Disorder and Fatal Opioid Overdose in 2017 at over 1 trillion dollars. *See State-Level Economic Costs of Opioid Use Disorder and Fatal Opioid Overdose — United States, 2017*, CDC.GOV (Apr. 16, 2021) https://www.cdc.gov/mmwr/volumes/70/wr/mm7015a1.htm.

[94] *See* Carrick Mollenkamp & Jonathan Stempel, *Standard Chartered May Lose NY License Over Iran Ties* (2012) https://www.reuters.com/article/us-standardchartered-iran-idUSBRE8750VM20120806.

proliferation opioids the U.S., the disparity between the stated legislative intent and the actual function of the DSCSA must be eliminated. The balance will determine whether the DSCSA can live up to its potential as the comprehensive pharmaceutical supply chain statute, or whether it will be relegated to a failed "***effort*** to crack down on"[95] supply chain misconduct.

Sincerely,

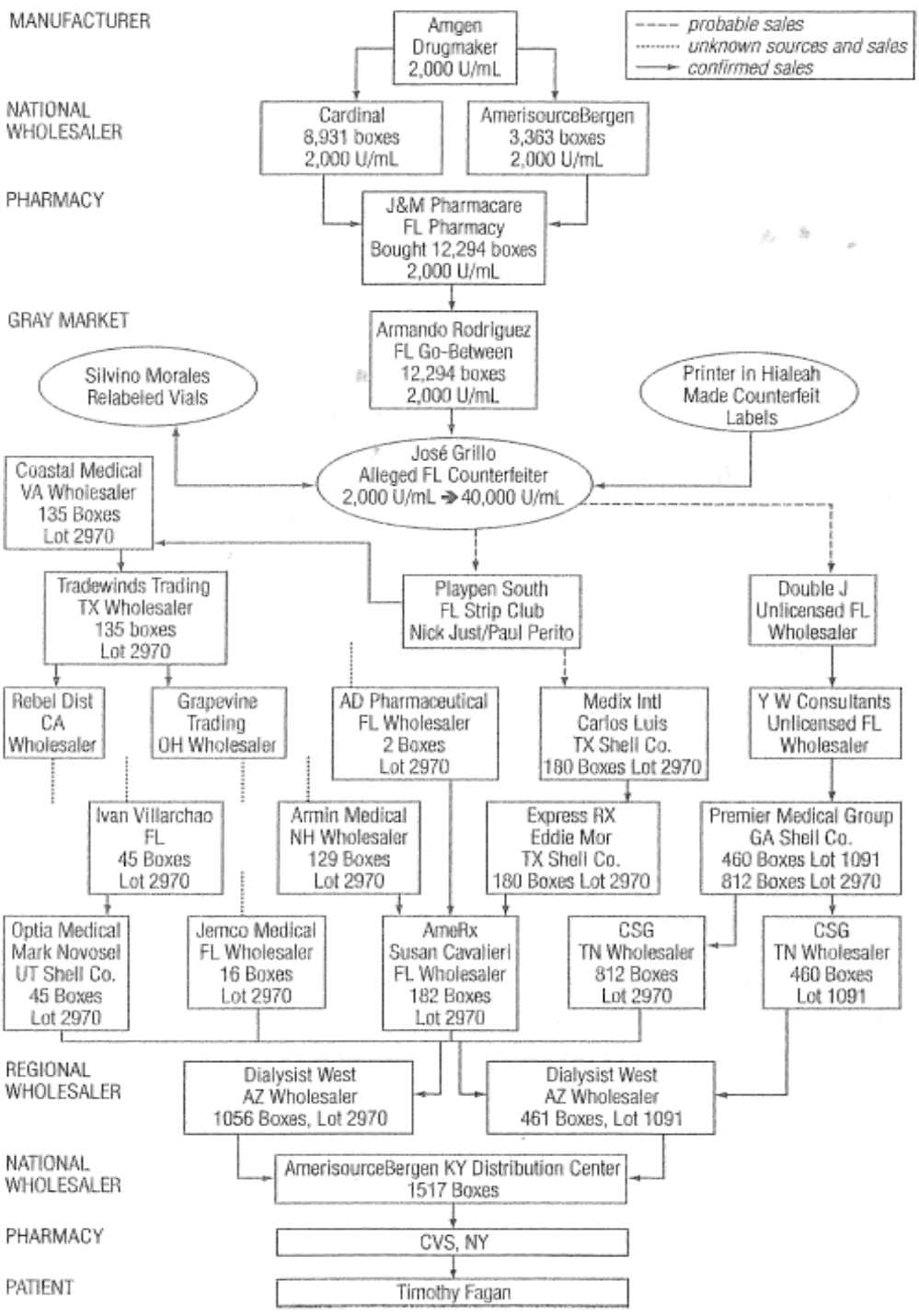
DocuSigned by:
Timothy M. Ward
0ED75F7D7419465...
9/6/2022

Timothy M. Ward, Esq.
President

[95] Walker & Ramey, *supra* note 23.

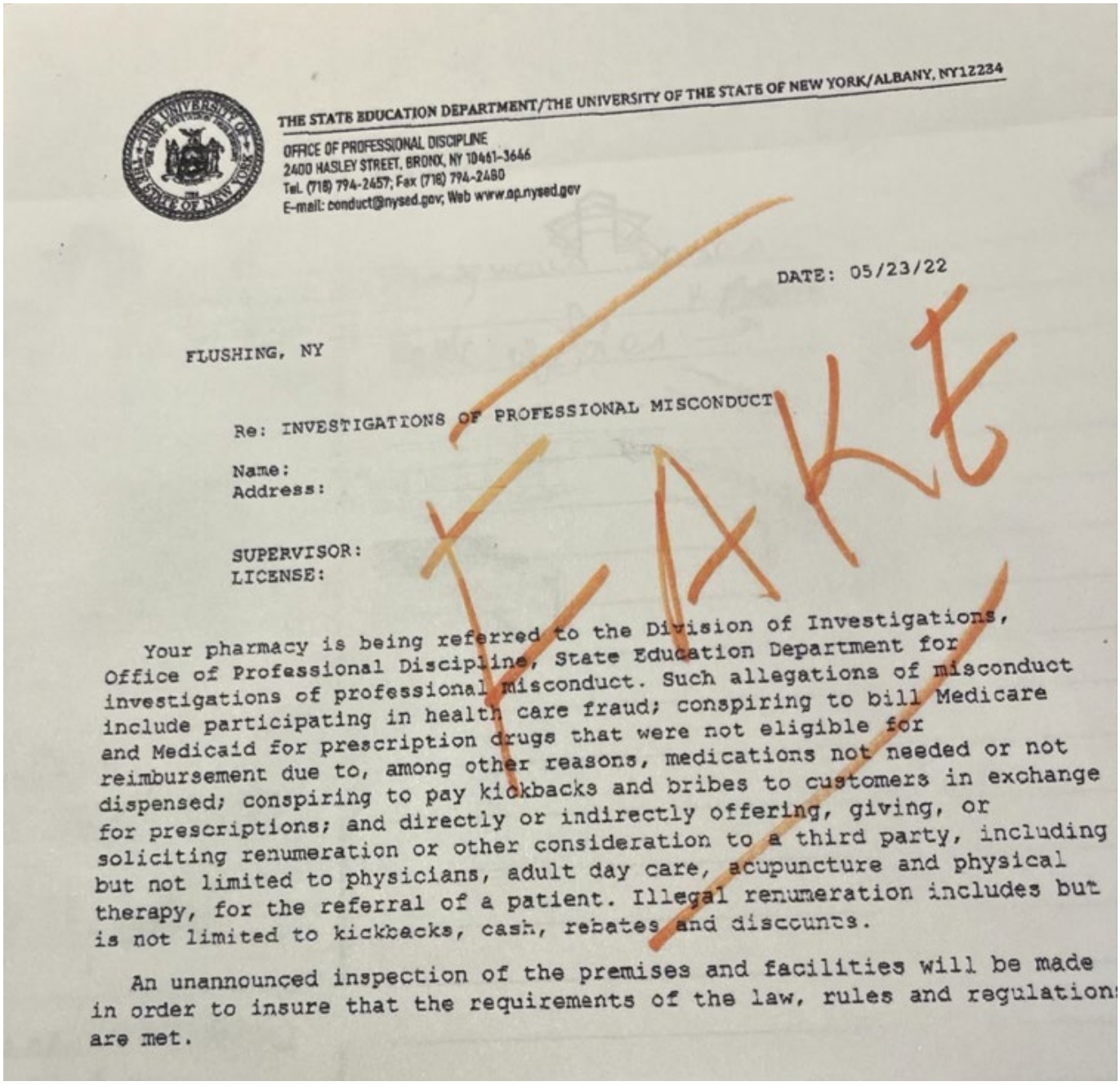
Addendum I

Katherine Eban, Dangerous Doses pg. 358 (2005)



ADDENDUM II

Scam Letter Posing as New York Office Of Professional Discipline



THE STATE EDUCATION DEPARTMENT/THE UNIVERSITY OF THE STATE OF NEW YORK/ALBANY, NY12234

OFFICE OF PROFESSIONAL DISCIPLINE
2400 HASLEY STREET, BRONX, NY 10461-3646
Tel. (718) 794-2457; Fax (718) 794-2480
E-mail: conduct@nysed.gov; Web www.op.nysed.gov

DATE: 05/23/22

FLUSHING, NY

Re: INVESTIGATIONS OF PROFESSIONAL MISCONDUCT

Name:
Address:

SUPERVISOR:
LICENSE:

FAKE

Your pharmacy is being referred to the Division of Investigations, Office of Professional Discipline, State Education Department for investigations of professional misconduct. Such allegations of misconduct include participating in health care fraud; conspiring to bill Medicare and Medicaid for prescription drugs that were not eligible for reimbursement due to, among other reasons, medications not needed or not dispensed; conspiring to pay kickbacks and bribes to customers in exchange for prescriptions; and directly or indirectly offering, giving, or soliciting renumeration or other consideration to a third party, including but not limited to physicians, adult day care, acupuncture and physical therapy, for the referral of a patient. Illegal renumeration includes but is not limited to kickbacks, cash, rebates and discounts.

An unannounced inspection of the premises and facilities will be made in order to insure that the requirements of the law, rules and regulations are met.