Hercules
your ethical wholesaler

Comments on the US Food and Drug Administration's Draft Guidance Documents:

(i) Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act ("Definitions Draft Guidance Document") [Docket No. FDA-2018-D-0338];

And

(ii) Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act ("EDDS Draft Guidance Document") [Docket No. FDA-2020-D-2024].

Background

In November 2013, President Barack Obama signed into law the Drug Quality and Security Act ("DQSA").[1] The DQSA amended the Federal Food, Drug, and Cosmetic Act ("FD&C Act") with respect to various aspects of the pharmaceutical supply chain. Title I of the DQSA, the Compounding Quality Act ("CQA") is primarily codified at 21 U.S.C. § 351 *et seq.* and regulates the registration and operation of compounding pharmacies and outsourcing facilities that compound drugs.

Title II, the Drug Supply Chain Security Act "(DSCSA), regulates aspects of the trade in pharmaceuticals. The DSCSA, amongst other requirements, primarily:

- obligates manufacturers to label products with a "product identifier" at the package and homogeneous case level;[2]
- obligates members of the pharmaceutical supply chain to limit the commercial trade of drugs[3] exclusively to "authorized trading partners" ("ATPs");[4]

[1] Drug Quality and Security Act, Pub. L. No. 113-54, § 102, 127 Stat. 587, 587-93 (2013) https://www.govinfo.gov/content/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf.
[2] 21 U.S.C. § 360eee-1(b)(2). A product identifier must include: 1) the National Drug Code; 2) a unique alphanumeric serial number; 3) the lot number; and 4) the expiration date. This information must be included in human readable and machine readable format. 21 U.S.C. §§ 360eee(14), (20).
[3] 21 U.S.C. § 360eee(12).
[4] 21 U.S.C. §§ 360eee-1(b)(3), (c)(3), (d)(3), (e)(3). A trading partner is 'authorized' under the DSCSA if licensed under the appropriate state or federal authorities, depending on the entity type. 21 U.S.C. § 360eee(2).

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- obligates that specific information concerning (i) products and (ii) their chain of ownership by ATPs be transmitted/communicated prior to, or concurrent with, the physical exchange of goods, or their transfer of ownership, by and amongst ATPs;[5] and

- obligates the functioning of electronic interoperable systems to facilitate the transfer of this information among ATPs by November of 2023.[6]

The policy goals embodied by the DSCSA are to keep our supply chain safe from drugs that are adulterated, counterfeit or otherwise unfit for consumption,[7] to keep the supply chain safe from criminal and fraudulent activity,[8] and that the DSCSA play a role in cost containment.[9] The DSCSA has helped the pharmaceutical industry conceptualize the possibilities of a safe and secure supply chain, operating to 21st century standards for the betterment of public policy goals. As the DSCSA federally preempted state drug pedigree laws it is incumbent upon us to craft a system worthy of the U.S. citizenry.[10]

Beginning in November 2023, product tracing must be conducted on an interoperable electronic system.[11] In furtherance of this goal, in June of 2021 the U.S. Food and Drug ("FDA") issued its "Definitions Draft Guidance Document" and its **"**EDDS Draft Guidance Document" which, with the DSCSA, serves as the basis of this instant comment.

Hercules Pharmaceuticals

Hercules Pharmaceuticals ("Hercules") is a nationally licensed primary[12] 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

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[5] 21 U.S.C. §§ 360eee-1(b)(1), (c)(1), (d)(1). This information includes "transaction information"; "transaction histor[ies]"; and "transaction statement[s]." *E.g.*, 21 U.S.C. § 360eee-1(b)(1)(A)(i).
[6] 21 U.S.C. § 360eee-1(g)(1).
[7] *See* 159 CONG. REC. H5961 (2013) https://www.congress.gov/113/crec/2013/09/28/CREC-2013-09-28-pt1-PgH5946-2.pdf ("[T]his legislation 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" [statement of Rep. Waxman (D-CA)]); 159 CONG. REC. S8074 (2013) https://www.congress.gov/113/crec/2013/11/18/CREC-2013-11-18-pt1-PgS8071-5.pdf ("What is perhaps not known to many people, however, is that in today's drug supply system, there is no standard process for oversight to trace drugs through the supply chain system and make sure they were in the right hands and properly stored the whole time … [p]eople often do not realize that drugs do not usually travel directly from a manufacturer to a pharmacist. In fact, they may make many stops along the way. Manufacturers, resellers, wholesalers, distributors—these are some of the entities that can receive, resell and ship drugs before they get to the pharmacist or patient. 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." [statement of Sen. Feinstein (D-CA)]).
[8] 159 CONG. REC. H5960 ("[The DSCSA is] a bill that will protect American patients by ensuring that they receive safe drugs … This legislation will strengthen the prescription drug supply chain in order to protect American families against counterfeit drugs . . . " [statement of Rep. Upton (R-MI)]).
[9] *Id.* ("[The DSCSA] also eliminates and prevents increases in drug prices." [statement of Rep. Upton (R-MI)]).
[10] *See e.g.*, 33 FLA. STAT. § 499.0121 (2004), https://www.flsenate.gov/Laws/Statutes/2004/499.0121.
[11] 21 U.S.C. § 360eee-1(g).
[12] SUSAN THAUL, CONG. RESEARCH SERV., R43106, 4 PHARMACEUTICAL SUPPLY CHAIN SECURITY (2013).https://crsreports.congress.gov/product/pdf/R/R43106/5 "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".

the patients.[13] 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) increases the risk that drugs are adulterated through excursions in environmental conditions during transit; and (ii) is the gateway practice for gray market sales[14] and other more complex financial schemes.[15]

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.[16] 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.

- **Comment on (i) *Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the DSCSA*[17]**

The FDA's "Definitions Draft Guidance Document" provides "guidance to interpret the terms used in the definition of *suspect product* . . . and . . . *illegitimate product . . .*to assist trading partners in meeting verification obligations."[18]

Hercules respectfully recommends that the FDA add "temperature excursion in excess of a drug's mandatory shipping and storage requirements" either within the definitions of "*suspect product*" and "*illegitimate product*" (see, ***bold and italics*** section in Option One below) or within the guidance on "**E. Unfit for distribution"** (, ***bold and italics*** section in Option Two below).[19]

Option One

SUSPECT PRODUCT—The term 'suspect product' means a product for which there is reason to believe that such product:

[13] 159 CONG. REC. S8024 (2013) https://www.congress.gov/113/crec/2013/11/14/CREC-2013-11-14-pt1-PgS8024.pdf ("The normal chain moves drugs from the manufacturer to a wholesaler to a pharmacy" [statement of Sen. Bennet (D-CO)]).
[14] *See id*. ("In the last decade this lack of oversight has created an enormous gray market in the United States of America." [statement of Sen. Bennet (D-CO)]).
[15] *See id*. ("The more times a drug goes back and forth and changes hands, the more opportunities criminals find to enter the system." [statement of Sen. Bennet (D-CO)]).
[16] 159 CONG. REC. S8075 (2013) https://www.congress.gov/113/crec/2013/11/18/CREC-2013-11-18-pt1-PgS8071-5.pdf ("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." [statement of Sen. Harkin (D-IA)]).
[17] U.S. FOOD & DRUG ADMIN., DEFINITIONS OF SUSPECT PRODUCT AND ILLEGITIMATE PRODUCT FOR VERIFICATION OBLIGATIONS UNDER THE DRUG SUPPLY CHAIN SECURITY ACT: GUIDANCE FOR INDUSTRY (Rev. 1, 2021) (draft) https://www.fda.gov/media/111468/download.
[18] *Id.* at 1.
[19] *Id.* at 5.

A. is potentially counterfeit, diverted, or stolen;
B. is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;
C. is potentially the subject of a fraudulent transaction; ~~***or***~~
D. is potentially the subject of a temperature excursion in excess of the drug's labeled mandatory shipping and storage requirements; or
~~***D.***~~ ***E.*** appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

ILLEGITIMATE PRODUCT—The term 'illegitimate product' means a product for which credible evidence shows that the product:

A. is counterfeit, diverted, or stolen;
B. is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;
C. is the subject of a fraudulent transaction; ~~***or***~~
D. is the subject of a temperature excursion in excess of the drug's labeled mandatory shipping and storage requirements; or
~~***D.***~~ ***E.*** appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

Option Two

"[The] … FDA interprets the term unfit for distribution as referring to a prescription drug whose sale would violate the FD&C Act and there is a reason to believe or credible evidence shows that the product would be reasonably likely to result in serious adverse health consequences or death to humans. This includes prescription drugs identified as suspect or illegitimate … including drugs rendered nonsaleable because conditions (such as return, recall, damage, ***a temperature excursion in excess of the mandatory shipping and storage requirements*** or expiry) cast doubt on the drug's safety, identity, strength, quality, or purity …; or misbranded … where there is a reason to believe or credible evidence shows that such product would be reasonably likely to result in serious adverse health consequences or death to humans.

A core aspect of a product's legitimacy is the assurance of its correct handling. Correct storage and handling of a drug (within its mandated handling instructions) is also part of the duty of care that each ATP owes to the ultimate beneficiary, the patient who receives the drug.

Please further consider that amongst the primary dangers of criminal diversion of pharmaceuticals is the adulteration of the medicine through improper storage and handling conditions. Consider the press release from U.S. Department of Justice's February 26, 2021 "*Pharmaceutical Business Owner Sentenced in Miami for Role in Prescription Medication Diversion Scheme*" which states:[20]

[20] Press Release, U.S. Dep't. of Just., U.S. Atty's Off. SDFL, Pharmaceutical Business Owner Sentenced in Miami for Role in Prescription Medication Diversion Scheme (Feb. 26, 2021) https://www.justice.gov/usao-sdfl/pr/pharmaceutical-business-owner-sentenced-miami-role-prescription-medication-diversion (emphasis added).

> "The illegally obtained prescription medications to treat conditions like cancer, HIV, and psychiatric illness ended up … ***in the hands of unsuspecting patients*** [and] ***[m]any of the drugs involved required storage in controlled conditions, the types of which usually do not exist during street drug exchanges***."[21]

The legitimate pharmaceutical supply chain must manifest the paradigm that is diametrically opposite to that of the criminal system, including assurance of the instructed storage and handling of medicine.

- **Comments on (ii) *Enhanced Drug Distribution Security at the Package Level Under the DSCSA* and *Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act*[22] and Related Aspects of the DSCSA.**

1. Comment *re:* "Data Errors"

The FDA's **"**EDDS Draft Guidance Document" is "intended to assist supply chain stakeholders, particularly trading partners, with requirements for enhanced drug distribution security at the package level under Section 582 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee-1), as amended by the Drug Supply Chain Security Act (DSCSA) (Title II of Public Law 113-54).[23]

Section V. Subsection D. is titled "**Handling Aggregation Errors and Other Discrepancies"** (Hereinafter "Sub-D"). Sub-D states in part:

> "If a wholesale distributor, dispenser, or repackager purchases product and ***identifies a potential clerical error or other discrepancy in the product tracing information it received***, that trading partner should ***resolve the error or discrepancy within 3 business days***."

Hercules recommends that FDA state that ***the selling trading partner must produce accurate transaction data prior to or concurrent with delivery, that purchasing trading partners must receive accurate transaction data prior to reintroducing the relevant products into the supply chain, and that discrepancies in transaction data must have a clear paradigm for reasonable reconciliation with obvious and shifting responsibilities.***

Hercules recommends that the FDA avail itself to the underlying legal paradigm governing the sale of goods aspect of these transactions to assure the requirements of the DSCSA. The

[21] *Id.* (emphasis added).
[22] U.S. FOOD & DRUG ADMIN., ENHANCED DRUG DISTRIBUTION SECURITY AT THE PACKAGE LEVEL UNDER THE DRUG SUPPLY CHAIN SECURITY ACT: GUIDANCE FOR INDUSTRY (2021) (draft). https://www.fda.gov/media/149704/download.
[23] *Id.* at 1.

underlying legal paradigm is the Uniform Commercial Code (UCC) Article 2 "Sales [of goods].[24] Hercules recommends a clear chain of responsibility and obligation for incorrect transaction data based on UCC Article 2 as follows:

The FDA should establish that all orders issued to a selling ATP, by a purchasing ATP, must be read to include all correct transaction data; in this way the FDA has guaranteed the incentive for transaction data to arrive correctly prior to, or concurrent with, the purchasing ATP receiving the goods. In the UCC Article 2 paradigm for a purchasing ATP to establish "acceptance"[25] of the "goods",[26] they must ensure that the "goods" conform to "tender"[27] meaning: (i) the correct transaction data has been received; and (ii) the suspect product analysis has successfully navigated. Failure to have accurate transaction data hence would operate as prohibition on "acceptance" and a hard stop on purchasing ATP moving the drug into their inventory for further sale or use by a patient.

Where incorrect or incomplete data is provided by the selling ATP, the next burden must be placed on the purchasing ATP to provide notice of the deficiency within a reasonable period of time (for example 10 business days after receiving the goods), which will shift the burden back again to the selling ATP who will be obligated to fix the data in a reasonable time (for example 30 business days), which under Article 2 of the UCC, is known as the "cure".[28]

Contouring DSCSA transaction-data-compliance to UCC Article 2 will provide certainty and incentivize parties to ensure the transaction data goals of the DSCSA in a reasonable amount of time. Selling ATPS shall be incentivized to efficiently treat transaction data as a co-product of the drug and purchasing ATPs shall be motivated to ensure that the transaction data is correct. Where transaction data is flawed, have clear responsible parties and insist upon a "cure" within a reasonable amount of time.

This recommendation is also consistent with the FDA's own draft guidance stating that a "fraudulent transaction" under the DSCSA is interpreted to mean "[any] transaction in which the transaction information, transaction history, or transaction statement contains information knowingly falsified by a trading partner."[29] How is a subsequent ATP to identify transactions as fraudulent if transaction information discrepancies are not required to be resolved by receipt of accurate data?

The allowance of a culture of bad compliance data to colonize the pharmaceutical supply chain raises the risk of that fraudulent transactions or knowingly false statements will go unrecognized.

[24] U.C.C. art. 2 (Am. Law Inst. & Unif. Law Comm'n 1951).
[25] U.C.C. § 2-606.
[26] U.C.C. § 2-105(1). *See also* 21 U.S.C. 360eee(13).
[27] U.C.C. § 2-301.
[28] U.C.C. § 2-508.
[29] DEFINITIONS OF SUSPECT PRODUCT AND ILLEGITIMATE PRODUCT, *supra* note 17, at 5.

2. Comment *re:* "Verification of Saleable Returned Product" and other risky blind spots in transaction data

Hercules Pharmaceuticals is highly concerned with the FDA's description of verification requirements regarding saleable returned product.[30] The DSCSA, as written, exempts dispensers[31] and repackagers[32] from transmitting transaction information, transaction history, and transaction statements when returning saleable product to the trading partner from whom it was purchased. Furthermore, when a wholesale distributor reintroduces that returned product into the supply chain, the transaction history for that product is permitted to *restart after* the acceptance of the return.[33] The only tracing activity that *must occur* in the context of a saleable return is that the wholesale distributor needs to correlate the product information on the drug label with prior transaction information in the possession of the wholesaler.[34]

This effectively permits a drug to be reintroduced into the supply chain with the fact of its prior return omitted from the transaction history; allowing the removal of any prior ATP ownership in the chain of custody has the effect of *data laundering*.

Hercules recommends that the FDA adopt the position that all ATPs who come into possession of a drug be listed in the transaction data and supplied to subsequent purchasers plus any ATP in privity to that specific product.

Hercules believes that this recommendation falls within the clear legislative intent of the DSCSA in regard to the traceability of a product. The healthcare provider should be given clear information about the handling of a product and how many times that product has been shipped and to whom. Should there be a value differentiation for products sold and returned and reshipped multiple times, that cost should be borne by the entity who made the decision (to purchase and then return the product) and not come at the expense of the awareness and decision making of the next healthcare provider purchases in good faith and upon DSCSA data.

Laundering returns data also significantly increases the risk of "returns abuse" by the wholesaler community against the manufacturing community. This financial scheme occurs when multiple

[30] ENHANCED DRUG DISTRIBUTION SECURITY AT THE PACKAGE LEVEL, *supra* note 22, at 13.
[31] 21 U.S.C. § 360eee-1(d)(1)(C)(i) ("A dispenser may return product to the trading partner from which the dispenser obtained the product without providing the information required under subparagraph (A).").
[32] 21 U.S.C. § 360eee-1(e)(1)(B)(ii) ("A repackager described in section 581(16)(B) [21 USCS § 360eee(16)(B)] may return a saleable or nonsaleable product to the manufacturer, repackager, or to the wholesale distributor from whom such product was received without providing the information required under subparagraph (A)(ii) on behalf of the hospital or other health care entity that took ownership of such product pursuant to the terms and conditions of any agreement between such repackager and the entity that owns the product.").
[33] 21 U.S.C. § 360eee-1(c)(1)(B)(i)(II) ("Beginning 6 years after the date of enactment of the Drug Supply Chain Security Act [enacted Nov. 27, 2013] (except as provided pursuant to subsection (a)(5)), a wholesale distributor may accept returned product from a dispenser or repackager only if the wholesale distributor can associate returned product with the transaction information and transaction statement associated with that product. For all transactions after such date, the transaction history, as applicable, of such product shall begin with the wholesale distributor that accepted and verified the returned product. For purposes of this subparagraph, the transaction information and transaction history, as applicable, need not include transaction dates if it is not reasonably practicable to obtain such dates.").
[34] *Id*.

sales and returns happen for the same bottle, for each sale a chargeback is initiated to manufacturer but not reversed on return. Requiring complete traceability at the unit level of all ATPs in privity of that drug will prevent such schemes. Enabling data-laundering under the moniker of "saleable returns" undermines the policy goals of the DSCSA by obscuring traceability and by failing to leverage traceability to allow the market to correct undesired behavior that drive drug costs up.

This Hercules recommendation also applies with equal force to the wholesaler-to-wholesaler transaction.[35] All ATPs who took possession of a unit level of a drug must be listed in the transaction data, and that data must be discoverable by upstream ATPs in privity. Drug diversion in the pharmaceutical supply chain often occurs downstream from wholesalers.[36] Allowing pharmaceuticals to travel in the supply chain without their true pedigree leaves the supply chain vulnerable to fraud, tampering, and other harmful crimes.[37] A wholesaler who sells a drug to another wholesaler is (in addition to increasing shipping risks to the drug) making the commercial decision to engage in that transaction, and any follow-on tracing requests is the cost of that business. The quality of the interoperable system should not suffer for that commercial choice. ***Wholesaler-to-wholesaler business transactions are precisely why we need the DSCSA.*** Hercules recommends that the FDA consider the risk of profit-seeking financial schemes that churn product around the pharmaceutical supply chain devoid of the goal that the medicine will ever be dispensed or administered.

Hercules believes that all such transaction data be present for non-saleable-returns[38] and discoverable by upstream ATPs. Such data will empower decision makers to analyze non-saleable-returns in a manner to create efficiency and to help reduce the cost of drugs.

An interoperable tracing system, that knowingly allows the laundering of information increases the risk to the pharmaceutical supply chain and increases the risk of financial schemes. The FDA should leverage the antiseptic quality of transparency and factual accuracy.

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[35] 21 U.S.C. § 360eee-1(c)(1)(B) ("(i)(II) Beginning 6 years after the date of enactment . . . a wholesale distributor may accept returned product from a dispenser or repackager only if the wholesale distributor can associate returned product with the transaction information and transaction statement associated with that product. For all transactions after such date, the transaction history, as applicable, of such product shall begin with the wholesale distributor that accepted and verified the returned product. For purposes of this subparagraph, the transaction information and transaction history, as applicable, need not include transaction dates if it is not reasonably practicable to obtain such dates. (ii) A wholesale distributor may return a nonsaleable product to the manufacturer or repackager, to the wholesale distributor from whom such product was purchased, or to a person acting on behalf of such a person, including a returns processor, without providing the information required under subparagraph (A)(i).") (emphasis added). *See also* 21 U.S.C. §§ 360eee-1(c)(1)(A)(iii, iv) ("(iii) If the wholesale distributor did not purchase a product directly from the manufacturer, the exclusive distributor of the manufacturer, or a repackager that purchased directly from the manufacturer, as described in clause (ii), then prior to, or at the time of, each transaction or subsequent transaction, the wholesale distributor shall provide to the subsequent purchaser a transaction statement, transaction history, and transaction information, in a paper or electronic format that complies with the guidance document issued under subsection (a)(2). (iv) For the purposes of clause (iii), the transaction history supplied shall begin only with the wholesale distributor described in clause (ii)(I), but the wholesale distributor described in clause (iii) shall inform the subsequent purchaser that such wholesale distributor received a direct purchase statement from a wholesale distributor described in clause (ii)(I).") (emphasis added).

[36] PROTENUS, 2021 DIVERSION DIGEST, 3–4, 7 (2021) https://www.protenus.com/resources/2021-drug-diversion-digest.

[37] *Supra* note 13, at S8024 ("The more times a drug goes back and forth and changes hands, the more opportunities criminals find to enter the system. In the last decade this lack of oversight has created an enormous gray market in the United States of America. Companies can stockpile drugs that are in high demand and sell them later at dramatically higher prices." [statement of Sen. Bennet (D-CO)]).

[38] *See* 21 U.S.C. § 360eee-1(c)(1)(B)(ii) ("A wholesale distributor may return a nonsaleable product to the manufacturer or repackager, to the wholesale distributor from whom such product was purchased, or to a person acting on behalf of such a person, including a returns processor, without providing the information required under subparagraph (A)(1).")

3. Comment *re:* "Protecting Confidential Commercial Information and Trade Secrets"

Hercules recognizes that the FDA is subject to the DSCSA's mandate and that it promulgate guidance documents ensuring the protection of "confidential commercial information". We offer the following commentary with the utmost respect for the FDA.

Hercules remains highly concerned around the unitary speech prohibition imposed on it as a "wholesale distributor."[39] Consider DSCSA § 582 which is titled "**REQUIREMENTS**"[40] and therein with subsection (c) that is titled "**WHOLESALE DISTRIBUTOR REQUIREMENTS**" which states:

> "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) and (iii), and, as applicable, pursuant to an agreement under subparagraph (D).[41]

It is Hercules position that this law is a facial restriction on its free speech rights.

Hercules seeks to communicate ***its*** proprietary confidential information with those trading partners in commercial privity-of-transaction to any serialized product, such as manufacturers, to ensure the policy goals of a safe and secure supply chain free of fraud and other crimes, and to provide those entities with the ability to audit transactions.

Hercules notes that other classes of authorized trading partners are not facially speech-restricted by the DSCSA, as is Hercules, a wholesale distributor. Further, other authorized trading partners can use third party service providers, to manage this data, without restrictions imposed.

The data that Hercules seeks to communicate (data which it owns and which concurrently falls under the DSCSA moniker of "confidential commercial information") represents speech offered to ensure compliance to the law, to facilitate auditing capabilities, and to facilitate the manifestation of public policy. While the terms, 'confidential commercial information' and 'trade secrets' are not defined in the DSCSA, the FDA implicitly interprets them to include "product tracing information" in the "EDDS Draft Guidance Document".[42]

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[39] 21 U.S.C. § 360eee(29).
[40] 21 U.S.C. § 360eee-1.
[41] 21 U.S.C. § 360eee-1(c)(1)(A)(v)(II) (emphasis added).
[42] ENHANCED DRUG DISTRIBUTION SECURITY AT THE PACKAGE LEVEL, *supra* note 22, at 7, n.19

It is Hercules' position that our compliance-based speech, communicated for the purpose of ensuring public policy is more significant than the notion of "commercial speech" discussed in paradigm known as the *Central Hudson Test.*[43] Yet even using *Central Hudson*'s intermediate scrutiny we cannot identify a government interest in the prohibition on communication of our data, to the manufacturers in privity with the unit level of the product.

Compounding the facial speech restriction contained in §582(C)(1)(v)(II), is the FDA's additional restrictions contemplated in the "EDDS Draft Guidance Document"*;* see section IV C:

> "C. Protecting Confidential Commercial Information and Trade Secrets
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> 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*** [**footnote 19** of that document] through usual business practices."[44]
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> [**footnote 19**: "For the purposes of this guidance, ***the term product tracing information refers to the transaction information, transaction history, and transaction statement associated with a product that is sold***."][45]

The FDA's "EDDS Draft Guidance Document" extends the §582(C)(1)(v)(II) facial restriction through further regulation of conduct that is sufficiently imbued with elements of communication as "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."***[46] The "enhanced system" is an ecosystem of technology belonging to Hercules and relevant other third-party ATPs in privity of transaction to any specific package of pharmaceuticals. Hence, should it be implemented "as is" Section IV. C of the "EDDS Guidance Document" shall function to prohibit conduct that is imbued with elements of speech within the paradigm of *Spence v. Washington.*[47] Hercules, and its chattels, (and other allied third parties and their chattels) would be restricted from conduct which failed to ***"protect confidential commercial information and trade secrets";*** specifically this would prohibit Hercules, a wholesale distributor, communicating

("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.").

[43] *See* Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 566 (1980).

[44] ENHANCED DRUG DISTRIBUTION SECURITY AT THE PACKAGE LEVEL, *supra* note 22, at 7 (emphasis added).

[45] *Id*. at 7, n.19 (emphasis added).

[46] *See id*. at 1, n.4.

[47] Spence v. Washington, 418 U.S. 405, 409 (1974)

its data to manufacturers for the purpose of achieving orchestrated compliance, audit and ensuring public policy.
COVID-19 has exposed the critical importance of the US pharmaceutical supply chain both as an asset of our system of health and as a national security asset. It is imperative that our supply chain is both ready to withstand normal commercial operations and be ready to serve this country when it is needed most.[48]

We thank the FDA for the opportunity to comment.

Sincerely,

Timothy M. Ward, Esq.
President.

[48] See, Admiral Foggo III, James G. "Germs: The Seventh Domain of Warfare." U.S. Naval Institute, 30 Apr. 2020, www.usni.org/magazines/proceedings/2020/april/germs-seventh-domain-warfare.

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