Published on *The National Law Review* https://natlawreview.com

Recent Supreme Court Decisions and the DSCSA

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The recent Supreme Court decisions of *SEC v. Jarkesy*[1] and *Loper Bright Enterprises v. Raimondo*[2] have the potential to meaningfully impact the implementation and enforcement of the Drug Supply Chain Security Act[3] ("DSCSA") as industry transitions away from the "stabilization period" ending on November 27, 2024.

The DSCSA statute contemplated that the Enhanced Drug Distribution Security system ("EDDS") was to be effective November 27, 2023.[4] Recognizing that many Trading Partners were not yet ready to fully comply with the November 27, 2023 deadline, in August 2023, the FDA issued a compliance policy guidance document with regard to EDDS.[5] This guidance document provided Trading Partners with a one-year "stabilization period", through November 27, 2024, during which the FDA would not enforce the statutory EDDS requirements.[6] The stabilization period was implemented to avoid supply chain disruption and to ensure continued patient access to prescription drug products, while Trading Partners continue to work towards compliance with the EDDS requirements.

As we move from the "stabilization period" to perhaps a period of greater enforcement, each of these decisions favor the potential positions of regulated trading partners over the FDA in application to the DSCSA.

SEC v. Jarkesy Overview

The *Jarkesy* case addressed the issue of whether the Securities and Exchange Commission ("SEC") can enforce civil monetary penalties against defendants through administrative law, even if a defendant demands a jury trial.[7] In finding that such a defendant is entitled to a jury trial under the Seventh Amendment, the Supreme Court held that civil monetary penalties are legal remedies, and any defendant who faces an enforcement action and remedy that is legal in nature, as opposed to equitable in nature, is protected by the Seventh Amendment right to a jury trial.[8]

As Justice Sotomayor's dissent noted, like the SEC, the FDA is one of a number of "federal agencies that can impose civil penalties in administrative proceedings."[9] This includes the FDA's authority to impose civil penalties for DSCSA violations through administrative proceedings.

Application of *Jarkesy* to DSCSA

The DSCSA makes clear that a failure to comply with the DSCSA is a violation of the Food, Drug and Cosmetic Act ("FDCA") and that a drug that does not include a DSCSA product identifier is a misbranded drug under the FDCA.[10] The FDCA, in turn, authorizes the FDA to impose civil monetary penalties for FDCA violations and provides for an administrative process for the FDA to enforce such penalties.[11]

Jarkesy likely removes the FDA's power to require that civil monetary penalty cases proceed through an administrative proceeding where the defendant asserts a right to a federal jury trial. For example, if the FDA seeks a penalty against a manufacturer who distributes a drug without a product identifier, that manufacturer could demand a federal jury trial. And there may be incentives to do so. Though the cost of litigation may be greater with a federal jury trial, a defendant in federal court is generally entitled to more procedural protections and rights. Moreover, a defendant may prefer to take its chances with a jury, which may look at a case much differently than an administrative law judge.

Speed to a final resolution of the enforcement action is another consideration. The administrative appeal process should generally be faster than federal litigation involving a jury. Perhaps, in some cases defendants may want a faster process, but in other cases, defendants may want to force the FDA to go through the slow process of federal litigation and potentially delay enforcement.

From the FDA's perspective, *Jarkesy* may be a disincentive for civil monetary penalties, as the FDA may want to avoid long federal trials and the cost thereof. At a minimum, the FDA may choose to reserve civil monetary penalty actions for only significant DSCSA violations.

The future of FDA DSCSA enforcement remains to be seen. However, the landscape for enforcement actions has definitely shifted under *Jarkesy* and may impact the FDA's plans for how it will approach enforcement, particularly given the upcoming end to the stabilization period and a shift away from implementation and possibly towards enforcement.

***Loper Bright Enterprises v. Raimondo* Overview**

The *Loper* case involved a regulatory challenge that the National Marine Fisheries Service (NMFS) did not have statutory authority to promulgate a rule imposing a self-monitoring regulatory cost on certain fishing vessels.[12] The Supreme Court remanded the case for further analysis and in the process overruled the forty-year old *Chevron*[13] deference standard, which had been relied upon by the lower courts in resolving the challenge.[14]

In overruling *Chevron*, the Court held that lower courts should "exercise their independent judgment in deciding whether an agency has acted within its statutory authority . . . and may not defer to agency interpretation of law simply because a statute is ambiguous."[15] In reaching this conclusion, the Court did preserve some level of respect for agency action, i.e., when Congress explicitly delegates authority to the agency, as long as the agency acts within such delegated authority.[16] The courts must ensure that the agency is operating within "the boundaries of the delegated authority" and has engaged in "reasoned decisionmaking."[17] Moreover, the Court held that an agency's interpretation may be informative for courts, especially "to the extent it rests on factual premises within [the agency's] expertise."[18] In other words, an agency has "the power to persuade, if lacking power to control."[19]

Application of *Loper Bright Enterprises* to DSCSA

To date, the FDA has only promulgated one proposed rule implementing the DSCSA, the Proposed Rule on National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers.[20] FDA statutory interpretations within what will become the Final Rule will fall squarely under the *Loper* standard of review, should a party choose to challenge any aspects of the Final Rule.

Beyond this Proposed Rule, the rest of the FDA's DSCSA implementation action has been taken largely through guidance documents, which expressly state that such guidance should only be viewed as a recommendation and is not legally enforceable. The latter should not be directly impacted by *Loper*, as the guidance documents are expressly nonbinding. Nonetheless, should the FDA rely on interpretations provided within these guidance documents and similar documents as part of any future rulemaking or as part of an enforcement action, the *Loper* standard must be considered.

In light of the *Loper* holding as to express congressional delegation of authority to an agency, the Final Rule, once issued, should be subject to more limited scrutiny provided the FDA remains within the bounds of its delegated authority and engages in reasoned decisionmaking; the DSCSA expressly delegates to the FDA the authority to establish wholesaler and third-party logistics provider ("3PL") licensing standards.[21] Nonetheless, were a challenge to the rule to arise, a court would still scrutinize the agency's interpretation to examine whether the FDA exceeded the scope of its delegated authority or did not making well-reasoned interpretative decisions under the *Loper* standard.

Within the Proposed Rule are a number of provisions in which the FDA seeks to interpret ambiguous terms within the DSCSA. First, the DSCSA provides that wholesaling does not include "the distribution of minimal quantities of drug by a licensed retail pharmacy to a licensed practitioner for office use."[22] However, the term "minimum quantities" is undefined. Within the Proposed Rule, the FDA interprets "minimal quantities" to be "5 percent of the total dollar volume of that retail pharmacy's annual prescription sales."[23]

Second, the FDA proposes a number of terminology definitions for terms, which were not defined in statute. The FDA states that it is defining such terms in order to clarify other statutorily defined terms that reference the FDA's proposed terms and to align with existing law and regulations. The FDA proposes definitions for the following terms: 3PL activities, change of entity ownership, co-licensed partner, designated representatives, entities, facility and key personnel.[24]

Third, the question as to what extent the federal wholesaler and 3PL licensing standards preempt state law has long been open to debate. The statutory language regarding federal licensure standards prohibits state laws that are "inconsistent with, more stringent than, or in addition to any requirements" under the DSCSA or the FDA's finalized regulations.[25] In 2014, the FDA issued guidance stating that DSCSA preemption for wholesaler and 3PL licensing was a floor and not a ceiling.[26] However, in the Proposed Rule, the FDA states that it reconsidered its earlier interpretation and now maintains that the preemption is complete, a floor and a ceiling.[27]

Each of these examples illustrate the potential for regulatory challenges that may not receive the same deference that the FDA anticipated when it first drafted the Proposed Rule two years ago. The preemption issue is of particular interest, given that the FDA has changed its own position on what the statutory language means over the years. It would not be surprising if the process for the FDA to finalize this Proposed Rule now moves even more slowly, as the FDA seeks to bolster its reasoning for the stances that it is taking within the Proposed Rule.

Another area where FDA interpretation may be subject to new challenges is through its waiver, exemption and exception ("WEE") process. While the DSCSA has expressly delegated to the FDA the authority to establish a WEE process, a case study demonstrates that in responding to WEE's and making decisions, the FDA has engaged in statutory interpretation of ambiguities at least once as a part of its WEE response.[28] While nothing in the DSCSA statute allows a trading partner to appeal a WEE denial to court, such FDA statutory interpretations are unlikely to go unnoticed and may become a focal point of future enforcement actions that rely on such interpretations.

In 2015, a group of stakeholders requested that the FDA exempt wholesalers from sending DSCSA transaction data to 340B Covered Entity purchasers of 340B replenishment drugs, so that wholesalers could transfer the data and the physical drugs products together to 340B contract pharmacies without sending the data to the Covered Entities.[29] The FDA denied the request.[30]

In supporting its denial, the FDA squarely addressed the definition of drug product "ownership" and "direct ownership" of a drug product, terms which are undefined in the DSCSA and which determine to whom a seller sends transaction data and who is or is not a trading partner.[31] The FDA opined on the definitional contours of both terms, analyzing congressional intent in the process.[32]

Accordingly, the FDA has engaged in statutory interpretation as part of at least one WEE process, and there is no reason to believe that it has not done so with other WEE requests. As stated previously, to the extent the FDA engages in statutory interpretation in WEEs—or even within guidance documents—and those interpretations become part of future enforcement actions against trading partners, the *Loper* standard may come into play. Accordingly, the FDA will, moving forward, want to take caution in how it approaches statutory ambiguities within WEE responses and guidance documents. The deference that it could once rely upon no longer exists.

ENDNOTES

[1] Securities and Exchange Comm'n v. Jarkesy,144 S.Ct. 2117 (2024).

[2] Loper Bright Enterprises v. Raimondo, 144 S.Ct. 2244 (2024).

[3] Drug Supply Chain Security Act, 21 U.S.C. § 360eee et seq.

[4] Drug Supply Chain Security Act, 21 U.S.C. 360eee-1(g).

[5] U.S. Food and Drug Admin., *Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act — Compliance Policies Guidance for Industry* (August 2023), https://www.fda.gov/media/171592/download.

[6] *Id.* at 5.

[7] *See* Jarkesy, 144 S.Ct. at 2126-27.

[8] *See* Id. at 2128-29.

[9] *See* Id. at 2173-74.

[10] *See* 21 U.S.C. 331(t) and 21 U.S.C. 352(cc).

[11] *See* 21 U.S.C. 335b.

[12] Loper Bright Enterprises, 144 S.Ct. at 2255-56.

[13] Chevron, U.S.A., Inc. v. Natural Res. Defense Council, Inc., 467 U.S. 837 (1984).

[14] Loper Bright Enterprises, 144 S.Ct. at 2273.

[15] Id.

[16] *See* Id.

[17] Id. at 2263.

[18] Id. at 2267.

[19] Id. at 2259.

[20] *See* 87 Fed. Reg. 6708 (February 4, 2022).

[21] 21 U.S.C. 360eee-2(b), 21 U.S.C. 360eee-3(d).

[22] 21 U.S.C. 353(e)(4)(E).

[23] 87 Fed. Reg. at 6711.

[24] *See* Id. at 6713-14.

[25] 21 U.S.C. 360eee-4(b).

[26] *See* 87 Fed. Reg. at 6735.

[27] *See* id.

[28] *See* 21 U.S.C. 360eee-1(a)(3).

[29] *See* March 1, 2016 Letter from Ilisa B.G. Bernstein, Pharm.D., J.D. to National Association of Chain Drug Stores, et al. at 1.

[30] *See id.*

[31] *See* 21 U.S.C. 360eee(23)(a). *See e.g.,* 21 U.S.C. 360eee-1(b)(1)(A)i).

[32] *See* March 1, 2016 Letter at 3-4.

National Law Review, Volume XIV, Number 228