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The following visual presentation is intended for use when accompanied by an oral presentation by an attorney from the Office of Chief Counsel. This presentation is not legal advice.





# Bumps, Potholes and Landmines

Navigating the Highway of  
Chemical Laws and Regulations



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# A Matter of Opinion

- Storage of chemicals at warehouses and in vehicles
    - Registration and the Warehouse Exception (21 C.F.R. § 1309.23(b)(1))
    - Distribute = Deliver (21 U.S.C. § 802(11))
- “At the time the SLC order is placed ... no one at Respondent’s [registered location] knows how much the store has purchased.” *Novelty*, 73 Fed. Reg. 52689 (2008)



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## Bump, Pothole, or Landmine?

“Respondent violated federal law by distributing from an unregistered location, but...discontinued this practice upon learning that it was a violation.”

*Mr. Checkout North Texas*, 75 Fed. Reg. 4418 (2010)

“Respondent’s disregard of the letter and continuation of its practice for some forty-four months makes its conduct especially egregious.” *Novelty, supra*



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# Effective Controls Against Diversion

- Distributing SLCPs to non-certified retailers
  - Retailer must be self-certified to lawfully sell SLCPs (21 U.S.C. § 830(e)(1)(VII))
  - Regulated person must verify the apparent validity of a business entity ordering a listed chemical (21 C.F.R. § 1310.07(b))



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## Bump, Pothole, or Landmine?

“Respondent’s procedures for verifying the legitimacy of its listed chemical customers were wholly inadequate to prevent diversion.” *Sunny Wholesale*, 73 Fed. Reg. 57655 (2008)

“Respondent distributes List I chemical products only to those businesses that have self-certified in compliance with the Act.” *Hilmes Distributing*, 75 Fed. Reg. 49951 (2010); See also *Novelty*, *supra*



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# Actions Against Regulated Sellers

- Retailers of SLCs may be issued an Order to Cease Selling if...
  - 3.6 gram violation (knowing without consulting logbook)
  - Blister pack violation
  - Selling without self-certification
  - Logbook violations
- Orders issued to 316 regulated sellers



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# Volume, Volume, Volume!

- “Respondent’s sales of list I chemical products clearly were excessive....” *Sunny Wholesale, supra*
- No “safe harbor.” Distributing small amounts of list I chemicals does not relieve registrants of the obligation to determine whether products are likely to be diverted. *Sunny Wholesale, supra*
- Failure to enforce internal policies on sales limits can lead to revocation. *Novelty, supra*



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## Bump, Pothole, or Landmine?

Distribution of SLCPs to one customer that seems excessive did not warrant revocation where circumstances created only a “suspicion of diversion.” *Hilmes, supra*

No “free passes.” Notwithstanding concerns about customer’s prior orders, Respondent continued to distribute to customer at a rate that was more than 11 times what its average customer ordered. *Novelty, supra*

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# Records and Reports

- Report suspicious transactions

**“A distributor has an affirmative duty to forgo a transaction if, upon investigation, it is unable to determine that the proposed transaction is for legitimate purposes.”** *Novelty, supra*

- Keep accurate records

Missing invoices, incomplete records, and wrong addresses were “serious recordkeeping deficiencies.” *Novelty, supra*

- Inventory not required, but...system to monitor receipt and distribution is required. *Sunny Wholesale, supra*



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# Bump, Pothole, or Landmine?

“Were the evidence limited to Respondent’s recordkeeping problems, imposing compliance conditions might well protect the public interest.”

*Novelty, supra*

Recordkeeping violations, in combination with inability to account for chemicals, warrant revocation.

*Sunny Wholesale, supra*



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# Keys to a Safe Journey

- Heed the posted signs
- Observe and respond to a changing environment
- Respond to the dashboard warning lights
- Watch out for other vehicles
- Heed the officer directing traffic

