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Disclaimer: The following written presentation was accompanied by an oral presentation from an attorney in DEA's Office of Chief Counsel. This presentation does not constitute legal advice to DEA registrants or other individuals. The Final Orders published in the Federal Register constitute DEA's official position on the cases and issues discussed in this presentation.

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## Legal Update: Lessons from Recent Cases

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## Agenda

Review of Final Orders

Summary of Key Lessons

Questions and Answers



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## Southwood Pharmaceuticals

72 Fed. Reg. 36487 (Jul 3, 2007)

The case of overlapping statutory factors

The case of “how much is too much?”

The case of “who’s your customer?”



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## Southwood Pharmaceuticals

72 Fed. Reg. 36487 (Jul 3, 2007)

- “...no process in place to determine the nature of a potential customer’s business before it sold to them.”
- “This is an obscene amount of drugs.”
- “...quantities that far exceeded what its traditional retail pharmacy customers ordered.”

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## Southwood Pharmaceuticals

72 Fed. Reg. 36487 (Jul 3, 2007)

- Maintaining effective controls against diversion is more than just good physical security, proper recordkeeping, and inventories that match records
- Understand your customers position relative to the rest of the industry
- Extraordinarily large volume can be a key indicator of diversion

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## Novelty Distributors, Inc.

\_\_ Fed. Reg. \_\_\_\_\_ (Sep \_\_, 2008)

The case of the principal place of business

The case of “how much is too much?”

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## Novelty Distributors, Inc.

\_\_ Fed. Reg. \_\_\_\_\_ (Sep \_\_, 2008)

- When shipped from the registered location  
“...the products have not been sold to a particular customer.”
- “...SLCs may remain on a salesperson’s truck for up to nine days.”
- “...a registrant cannot ignore evidence that some of its customers are purchasing quantities that greatly exceed what it typical customer buys...”

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## Novelty Distributors, Inc.

\_\_ Fed. Reg. \_\_\_\_\_ (Sep \_\_, 2008)

- “Fundamental to its obligation to maintain effective controls against diversion, a distributor must review every order and identify suspicious transactions. Further, it must do so prior to shipping the products. Indeed, a distributor has an affirmative duty to forgo a transaction if, upon investigation, it is unable to determine that the proposed transaction is for a legitimate purpose.”

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## Novelty Distributors, Inc.

\_\_ Fed. Reg. \_\_\_\_\_ (Sep \_\_, 2008)

- Maintaining effective controls against diversion is more than just good physical security, proper recordkeeping, and inventories that match records
- Know precisely what each customer is ordering before shipping from the registered location
- Storage in trucks can be a problem

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## Novelty Distributors, Inc.

\_\_ Fed. Reg. \_\_\_\_\_ (Sep \_\_, 2008)

- Extraordinarily large volume can be a key indicator of diversion
- “DEA has frequently found that the listed chemicals which are used by smaller illicit labs have been sold by convenience stores, gas stations, and other small retailers.”

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## Holloway Distributing

72 Fed. Reg. 42118 (Aug 1, 2007)

The case of “be careful when you leave here”

The case of “how much is too much?”

The case of know your customer -- and his suppliers

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## Holloway Distributing

72 Fed. Reg. 42118 (Aug 1, 2007)

- “...see no evil, hear no evil -- is fundamentally inconsistent with the obligations of a DEA registrant.”
  - Respondent sold products “ which were far in excess of the normal retail sales by a non-traditional retailer to meet legitimate demand.”
  - Respondent sold listed chemicals to what Respondent’s employees called “the drug guy.”
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## Holloway Distributing

72 Fed. Reg. 42118 (Aug 1, 2007)

- Understand your customers position relative to the rest of the industry
  - Extraordinarily large volume can be a key indicator of diversion
  - Watch out for other warning signs: location of customer, cash transactions, etc...
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## Summary

- Distribute only from your registered location
- Screen orders before distribution
- Forgo transactions that cannot be determined to be legitimate
- Know your customer's legitimate need
  - Relative to the industry as a whole
  - Relative to your customer's segment of the industry
  - Relative to your other customers
- Know your customer's suppliers
- Know your customer – self-certification



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## Q and A



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