Background Material
Independent Distributor Industry Survival Challenged in 2012 by “Gray Market” Branding

United States Senate Commerce Committee
Hearing July 25, 2012

NCPD National Coalition of Pharmaceutical Distributors

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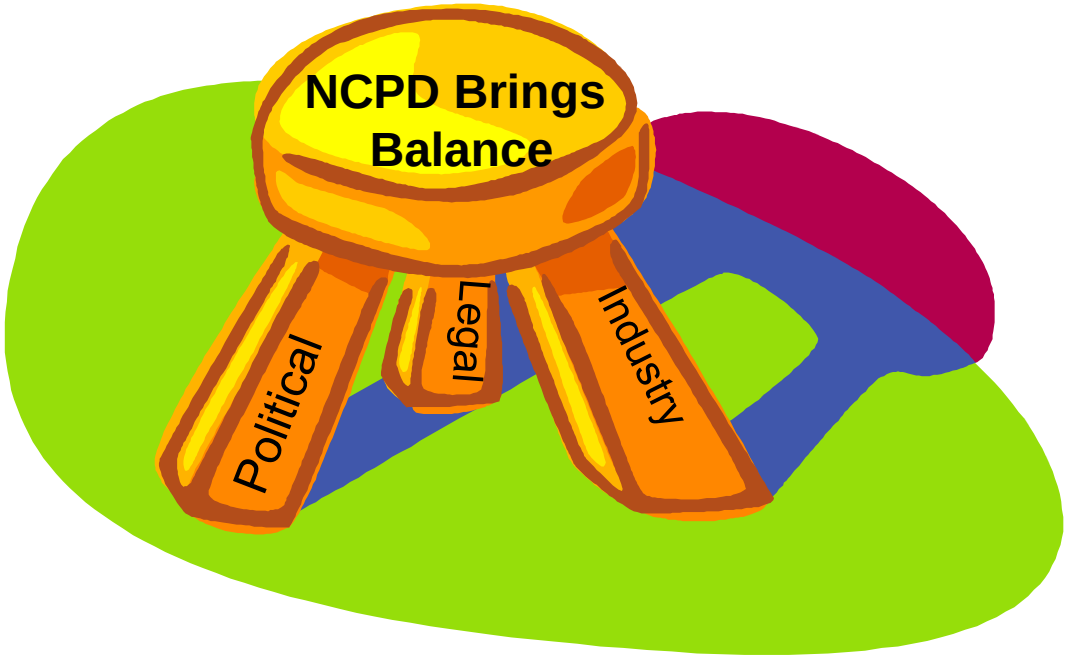
2006 National Coalition of Pharmaceutical Distributors Stood up and Fought for Orphaned Small Distributor ‘s Existence at FDA



Outreach for Industry, Policy Makers and Legal Protection

NCPD National Coalition of Pharmaceutical Distributors

Who is the NCPD?

- Small, independent, reputable distributors that are regulated by the FDA, the DEA and every state in which we operate
- Produce pedigrees for all Rx products distributed
  - Range from 100,000 – 1,000,000 and more annually
- Engage in current good manufacturing practices
  - VAWD Certified through National Boards of Pharmacy
- Provide heightened product quality assurance
  - Follow same warehouse SOP and shipping as BIG3
- NCPD members adhere to bright, black and white regulations

Basic Principles of Supply and Demand

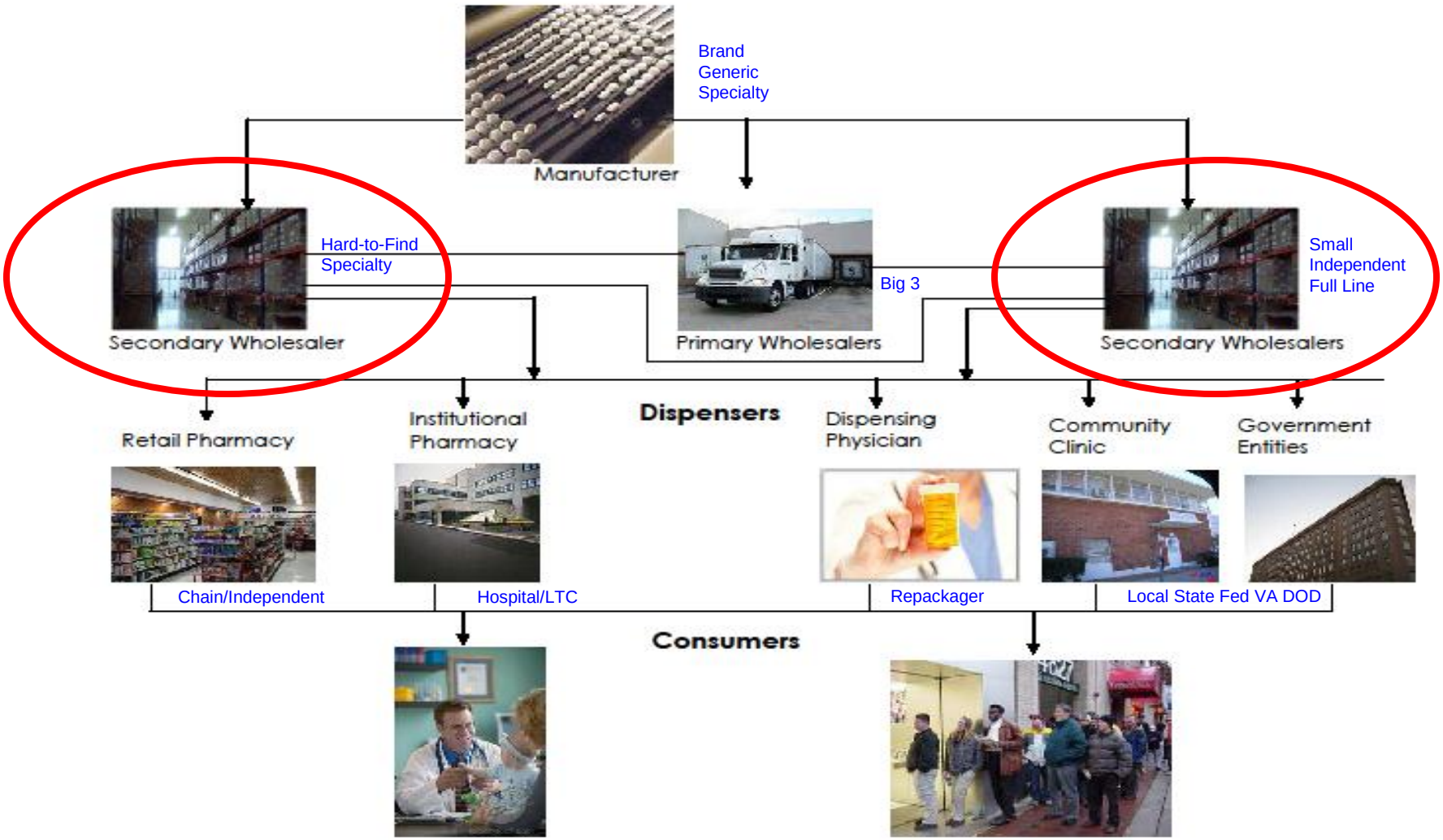
- The healthcare market is not immune to the basic principles of supply and demand. Supply represents how much the market can offer. The quantity supplied refers to the amount of a certain drug manufacturers are willing to supply when receiving a certain price. Price is a reflection of the supply and the demand. When there is a shortage, bad actors try to take advantage of the situation.
- NCPD members do not engage in price gouging behavior even though market conditions are ripe for it because they know it is inherently bad business to “gouge” customers that you want to come back and buy from you next week.
- You can’t stay in business long unless your prices are fair and competitive and that is how NCPD members have done business with their long-standing relationships.

Small Distributors Act in a Clearinghouse Capacity to Fill the Gap for Shortages

- Dr. Scott Gottleib, former FDA Administrator gave supporting testimony in Senate Finance Hearing on 12/7/2011 that this industry has been providing a ***"clearinghouse to reallocate the finite stock of drugs remaining when manufacturer has no supply to ship."***
- They can react quickly when bottlenecks created by the largest distributors are not able to supply.
- Certainly, "big" has advantages for the system, but to unfairly drive small distributors out of the supply chain will hurt providers and patients given the fact that they have been the only reliable, licensed sources for reallocating product in many life-saving situations.

2011Pharmaceutical Distribution Channel

$307B U.S. Product Supply Chain **



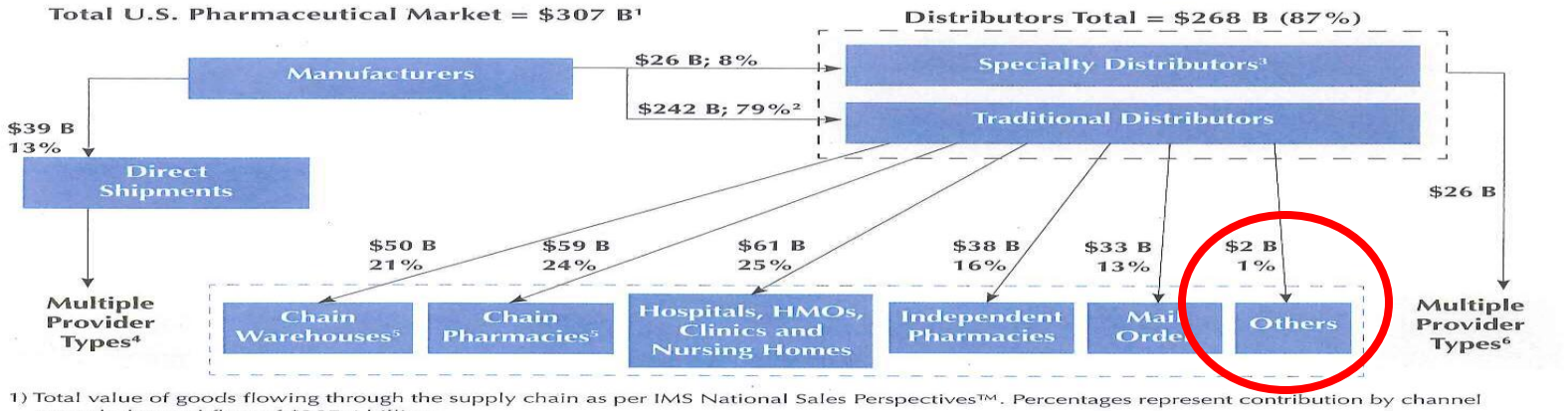
**See HDMA 2011-2012 Factbook & "The Role of Distributor in U.S. Healthcare Industry

Drug Distribution is a Complex Market with Many Key Players

Prescription pharmaceutical sales revenue moving through all distributors increased at a CAGR rate of 5 percent between 2006 and 2010. Significant growth in the generic and specialty drug segments drove this increase. The growth of the specialty segment,[8] at 69 percent CAGR, was particularly explosive — the fastest-growing category in pharmaceuticals. In fact, industry observers expect this to represent 50 of the top 100-selling drugs by 2016.[9] Generic drug sales revenue flowing through distributors grew at 5 percent rate, and this segment is expected to continue to grow — at an 8.6 percent CAGR between 2010-2014[10] — as more branded drug patents expire and additional demand shifts to generic products.

Figure 4 shows the multiple providers by sales volume that distributors serve in the healthcare supply chain.

FIGURE 4: Flow of U.S. Prescription Sales ($B) and Contribution by Channel (%) in 2010



1) Total value of goods flowing through the supply chain as per IMS National Sales Perspectives™. Percentages represent contribution by channel towards the total flow of $307.4 billion.
2) Total value of goods flowing through traditional distributors, *2011-12 HDMA Factbook* (Tables 1 and 3) — excludes all non-prescription products, and sales to other distributors.
3) Specialty distributors' sales and definition from Center for the Healthcare Supply Chain Research. *2010 Specialty Pharmaceuticals: Facts, Figures and Trends*, 2010.
4) Manufacturers ship directly to multiple provider types, including those served primarily by pharmaceutical distributors.
5) Chain pharmacies include national and regional drug store chains, mass merchandisers and food stores. Chain warehouses represent centralized warehouses for chain pharmacies.
6) Specialty distributors provide services to many provider types, including physicians' offices and clinics, home care providers, hospital pharmacies and specialty pharmacies.

Sources: Center for Healthcare Supply Chain Research. *2011-12 HDMA Factbook* (Tables 1, 3 and 109), IMS Health, Inc., Booz & Company analysis

[8] Specialty products are generally defined as products having four or more of the following characteristics: typically high cost ($600 or more per month); require special handling, storage and delivery; generally biologically derived; available in injectable, infused and occasionally oral forms; dispensed to treat individuals with chronic or rare diseases; have complex treatment regimes that require ongoing clinical monitoring and patient education; frequently have limited or exclusive product availability and distribution; used to treat therapeutic categories such as oncology, autoimmune/immune and inflammatory conditions.
[9] Walgreens Analyst Day report November 2010, IMS Health, Inc.
[10] Datamonitor, Global Generics report 2010.

See The Role of Distributors in U.S. Healthcare Industry, A 2011 study prepared Booz & Company, HDMA 2011-12 Factbook

GRAY MARKET DRUG REFORM AND TRANSPARENCY ACT of 2012

- Drug distribution is a complex market with many key players. Secondary distributors fill a gap that the large distributors can't service.

- Service less profitable rural regions and smaller providers that the large players will not service (i.e. minimum $20,000 - $50,000 monthly).

- Are required to pay much higher prices than large distributors which often receive chargebacks and rebates under large GPO contracts.

- Small distributors are "blocked/restricted" by the manufacturers and the GPO's from selling these contract items at the exclusive, often artificially-loss leader contract pricing between GPO and selected partners.

- Comparing prices offered under GPO contracts to those offered by small distributors is like comparing Walmart to the corner mom-and-pop store.

What is NCPD Trying to Accomplish?

- NCPD supports federal pedigree legislation. Its members are the only companies required to authenticate drugs and pass pedigrees since 2006.
- Supports the serialization of drugs for national track and trace system both at lot level and with 2D bar codes. Many of its members serialize drugs today for tracking and billing purposes where distribution in small unit of use packs.
- Actively lobbying since 2006 in support of stringent federal licensure standards and penalties for those who fail to comply with laws and standards
- Condemns all activities by gray market including stealing and selling drugs, “fake pharmacies” buying back drugs and reselling them, stockpiling drugs that are needed and gross “profiteering.”

Role of NCPD Member in Distributing Short-Supply Drugs

- Served as back-up, secondary, safety-net.
- Many drugs were being rationed by manufacturers and large wholesalers.
- Member buys from same wholesalers.
- They were rationed due to size and accounts closed by wholesaler due to negative publicity.
- They had to find new suppliers and use multiple distributors when purchasing product for hospitals.
- Accepted higher mark-ups on critical products in order to fill the immediate need of a hospital.

Pricing Perception is Not Reality

Small distributor does not “profiteer” and full analysis data will dispel claims that price gouging is normal business practice:

- Estimated revenues are about $13Mil.
- Average net operating income is about 7.5%
- Average products shipped are 144,000 units yr.
- Average products with pedigrees 144,000 yr.
- Average cost of drugs is approximately $90 unit.
- If mark-up was 200% per unit, would have net operating profits in excess of $20 Mil.
- None of NCPD members have reported net operating profits in excess of 10% of revenues. Many report losses.

NCPD Condemns Fake Pharmacies

- The NCPD does not support bad actors that create fake pharmacies in order to buy drugs from large wholesalers as a retail pharmacy and then resell the products as an intra-company transfer that re-distributes those same products into the U.S. supply chain.
- This is not a legitimate industry practice that is supported by the NCPD or its members.
- These incidents are not common practice and should not be used to punish the companies that do all the right things.

Pharmacy - Distributor Five Percent Rule

- State laws vary broadly in implementing 5% rule.
- Some states will allow a combo license – retail pharmacy/wholesale distributor license .
- NCPD and its members support all state laws and licensing provisions and adhere to them.
- Practical reality of the drug rationing situations during short-supply periods has driven some distributors to utilize the 5% rule to acquire drugs that were needed to meet their customer's needs in critical, life-threatening situations

We Oppose a “One-Touch” System

- NCPD opposes a “One-Touch” system which would mandate that distributors only buy product from an original manufacturer, such as Pfizer, Teva or J&J etc.
- One-touch would prevent distributors from buying products from Authorized Distributors of Record such as AmerisourceBergen, Cardinal or McKesson because the product would be “touched twice” by two distributors before it was sold to a hospital, clinic or physician’s office.
- NCPD members are small purchasers of pharmaceuticals and large manufacturers use the Authorized Distributor of Record (ADR) system to distribute products and require that small distributors purchase from an ADR.

Why Do We Oppose This System?

- This system will eliminate pharmaceutical distributors and, in turn, preclude small clinics and doctors' offices from buying necessary medication.
- Moreover, eliminating pharmaceutical distributors will add to the anti-competitiveness rampant in our health care market.
- It won't fix drug pricing concerns or cure the drug shortage.
- It would create an oligopoly, and you know happens to prices when that happens.

Drug Prices – Price Gouging False Allegations

- Premier Healthcare Alliance's Analysis "Navigating Drug Shortages in American Healthcare" March 20, 2011, Coleen Cherico, et al. leveled an accusation at "gray market" distributors (price gouging).
- As a result of this report and a follow up article, Buyer Beware Drug Shortages Opening Door to Price Gouging by Mike Alkire, Premier Inc. Oct. 15, 2011, "the secondary distributor industry is experiencing yet another unjustified attack on the business integrity of serving small, rural, underserved health care providers, just like them."
- It is disingenuous for Premier to attack secondary distributors, who must pay significantly higher prices for the same drugs that Premier's exclusive distributors get to sell at extraordinarily low contracted prices.

Drug Prices – Deeper Background

- Drug prices are established on an intricate system that is far more complex than most free markets
- Manufacturers set a number of price points for a product, including Wholesale Acquisition Cost (WAC) – lowest price a small distributor can buy the product
- GPO's leverage collective buying power when negotiating with the manufacturers
- Large distributors buy at WAC and sell at GPO contract then get reimbursed from manufacturers to make them whole in transactions
- Small distributors do not receive reimbursements from manufacturers or GPO pricing even if they sell same product to the exact same hospitals
- Loss leaders by GPO who benefits from system is distorting the market. Shortage appears, NCPD member fills need and the appearance is worse than reality

Small Distributors Inaccurately Portrayed in Price Gouging Accusations…

- The Premier “study” unscrupulously implies that all small distributors are “gray market” because they charge exorbitant mark-ups. Premier omitted the fact that their own exclusionary contracts forced small distributors to pay the highest price from the manufacturers.

- The reality is that smaller pharmaceutical distributors in the U.S. are legitimate, licensed, and highly regulated secondary suppliers to hospitals that need expedited orders.

- In fact, these secondary suppliers have provided a “safety-net” for hospitals when the designated, exclusive primary wholesaler has run short of critical drugs. In other words, when a product is in short supply, secondary distributors fill orders at reasonable mark-ups that are negotiated with their long-standing customers, but without the advantage of the lower, negotiated GPO prices.

- Distributors want repeat business. If seen as gougers, would not get repeat orders. Normal course of business is modest mark-ups.

Premier Reports Uses Threat Tactics to End Business Relationships

- Small distributors buy up available supplies and offer to see them to end purchasers at significantly higher prices
- Going after secondary distributors, now labeled as “gray market” because they have been forced to deal with “hard-to-find” medications.
- They have been labeled “gray market” companies indicating that how they practice business is not illegal, but may have a questionable business model.
- Unsubstantiated accusations are that they hoard medications and prey on institutions desperate for these medications.
- By selling these short supply meds at an exorbitantly higher price than the usual contract price.
- Not the real story.

"Premier has not revised their numbers or provided their analysis"

- Premier submitted this statement on Nov. 29, 2011 to NCPD when asked to put out a corrected press release…
- "To compute the markups, we compared Premier's contracted price to the gray market price. In the case of Pharmaceutical Commerce, the reporter asked whether markups were still significant if they were compared to a vastly more expensive metric – the Wholesale Acquisition Cost (WAC). We were specifically asked if we still saw pricing gouging if we compared the gray market price to WAC. WE DID."
- Even using much high WAC price comparison, we found the gray market marking up propofol between 29% and 729%.
- Premier stated "We deliberately did not use WAC as the comparison in our report because hospitals do not pay WAC for drug products. The calculations in our report are more reflective of the added costs being passed to hospitals, consumers and other payors by the gray market."

Premier Intentionally Distorted Facts

- The failure to use WAC in the comparison is misleading because, as Premier knows since they created the policy, secondary distributors must pay the actual WAC price because of Premier's monopolistic, exclusive practices.
- To not acknowledge the fact that they ignored WAC is leaving out an important, critical element of the analysis. Secondary distributors must pay WAC and to ignore it is an intentional distortion the facts.
- It is disingenuous for Premier to attack small distributors, who must pay significantly higher prices for the same drugs that Premier's exclusive distributors get to sell at extraordinarily low contracted prices.

Effects of Anti-Competitive GPO Practice Lessening Competition

- Manufacturers bid low prices in exchange for sole source GPO awards
- One supplier then corners the market for multiple years of contracts
- Artificial price controls drive competition to discontinue that product
- Limited distribution conspires to drive drugs into commodity exchanges
- Artificially low pricing leads to unnecessary shortages

Propofol is the generic version of Diprivan, the anesthetic drug used in Hospital Operation Rooms

Price: When No-Adverse Market Supply Issue:	**On Major GPO Contracts**
Manufacturer **A** Published Wholesale Acquisition Cost (WAC)	$5.60
GPO Contract Price	**$0.48**
Discount off Published Wholesale Acquisition Cost (WAC)	$5.12
Percent Discount Savings	**91.43%**

Actual Pricing that a Small Distributor Pays for Propofol when Purchasing for Normal Supply

Price Between Two Distributor Trading Partners, i.e. an ADR to Distributor	**No GPO Contract**
The WAC Price to Authorized Distributors	$5.60
ADR Invoice Price to Small Distributor	**$6.60**
Cost Plus Invoice Price to Distributor	$1.00
Percent Markup on ADR to Distributor	**17.86%**

Selling Price that a Small Distributor Offers to Hospital at15% Markup on its Purchase Price

Price If Market Supply Channel is Disrupted:	**Market Price**
Small Distributor Acquisition Price from ADR	$6.60
Sell Price to Hospital - Non GPO Eligible	**$9.25**
Cost Plus Mark-up on Sale to Hospital	**$2.65**
Percent Markup on Small Distributor Price	**40.15%**

This Illustration Shows a 40% Markup to Cover the Costs of Picking, Packing, Handling and Shipping Transactions for Propofol… $2.65 for all services

Cost Impact on hospital pricing as reported to GPO:	**On vs. Off Contract**
GPO negotiated contract price on APP product	**$0.48**
Non-GPO authorized distributor sale at WAC+	**$9.25**
Additional Cost to Purchase Off-Contract Alternative	$8.77
Cost Impact for hospital reporting to GPO	1827%

Anti-Competitive Leveraging Disadvantage to Small Distributors

- Manufacturer limited contract price and chargebacks to GPO-designated Wholesaler ONLY.
- Manufacturer and ADR set price to small distributor.
- Manufacturer and GPO restrict contract pricing to ADR's only.
- Non-GPO sale is WAC plus reasonable mark-up by small distributor.
- May include higher mark-up% for UPS Overnight, special handling, hazardous, refrigerated.

Conclusion

- NCPD members abide by bright black and white regulations.
- We condemn “gray market” activities and “fake pharmacies” black market activities.
- NCPD members would like to have level playing field to access contract prices – especially in times or national shortages.
- We support the pedigree standard with enhanced licensure standards and penalties for distributors that fail to comply with laws and standards.

Thank you on behalf of NCPD for your time and efforts to listen to the small distributors

NCPD | National Coalition of Pharmaceutical Distributors

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Patricia Earl, Principal and CEO, Secure Pharma Distributor Network leverages more than twenty six (26) years of senior executive pharmaceutical wholesale distribution industry experience, primarily at AmerisourceBergen to bridge large and small distributors issues and manufacturers to small distributors contracts.

As an industry veteran, she is recognized as an SME in her field and has served as an expert witness in recent federal court cases involving pharmaceutical wholesale distribution of counterfeit and adulterated drugs.