Report of the Task Force on Drug Diversion through Institutional Outlets

Members Present:
Wicki Erickson (TX); David Flashover (NY); Donald Gibson (MN); Susan Ksiazek (NY); and Wallace Nelson (NC).

Others Present:
Donna S. Wall, Executive Committee Liaison; Carmen Catizone, NABP Executive Director/Secretary; Melissa Madigan, NABP staff.

Technical Consultants:
Keith Macdonald, Nevada State Board of Pharmacy; C. Richard Allen, Georgia Drugs and Narcotics Agency; Margaret O’Rourke and Patrick Durkin, Food and Drug Administration (via conference call).

Absent:
John Taylor, chairman (FL).

Introduction:
The Task Force on Drug Diversion through Institutional Outlets met December 14 and 15, 2000, at the Marriott Suites Hotel in Rosemont, Ill. In the absence of John Taylor, Donna Wall chaired the meeting. The appointment of this Task Force came at the direction of the NABP executive Committee in response to Resolution 96-5-2000, Drug Diversion through Institutional Outlets, which was passed by the delegates to NABP’s 96th Annual Meeting, May 10, 2000, in Nashville, Tenn. The resolution reads as follows:

96-5-2000: Drug Diversion through Institutional Drug Outlets
Whereas, diversion of prescription pharmaceuticals has been found to be an extensive enterprise affecting the safety, quality, cost, and availability of those products to consumer, thereby endangering the public health and welfare; and
Whereas, diversion occurs because of certain marketing practices of some manufacturers and wholesalers, including the ability of certain institutions to purchase drugs at discounted prices; and
Whereas, federal indictments have identified individuals and institutions that engage in these activities and provide an indication of the extent to which these activities occur;
Therefore be it resolved that NABP request a federal investigation and intervention into prescription drug diversion through institutional drug outlets by the appropriate federal agency and encourage the Food and Drug Administration (FDA) to increase its efforts to eradicate these practices.

Review of the Task Force Charge
Task Force members reviewed their charge and, proposing no changes, accepted it as follows:
Examine the character and extent of practices employed by some manufacturers and wholesalers that have been shown to lead to the diversion of prescription pharmaceuticals through institutional outlets and propose solutions for addressing identified concerns.

**Discussion**

Task Force members observed presentations by Keith Macdonald, executive director of the Nevada State Board of Pharmacy, and Rick Allen, deputy director of the Georgia Drugs and Narcotics Agency, addressing the resale of pharmaceuticals purchased by pharmacies at preferential prices.

Traditionally, pharmaceutical manufacturers sell their products at significantly discounted prices to pharmacies servicing certain populations; for example, inpatients, long-term care patients, etc. Manufacturers are under no obligation to sell to these entities at preferential prices but do so through “own use” contracts in an effort to get facility patients started using their products at the point of therapy initiation. Preferential prices can span a wide range, with some entities receiving as much as 99% off the price paid by entities that do not receive such discounts (eg, retail pharmacies).

Deep discounts like this create a secondary market for these for these products, with entities that receive discounts reselling the products, at a significant profit, to purchasers not eligible for the discounts. The Prescription Drug Marketing Act of 1987 (PDMA) amended the Federal Food Drug, and Cosmetic Act to prohibit, with some exceptions, the sale, purchase, or trade of prescription drugs by “hospitals or health care entities” (those entities that receive the major discounts). The Food and Drug Administration (FDA), in its regulations implementing this legislation, defines a “health care entity” as “any person that provides diagnostic, medical, surgical, or dental treatment, or chronic or rehabilitative care, but does not include any retail pharmacy or any wholesale distributor. A person cannot simultaneously be a ‘health care entity’ and a retail pharmacy or wholesale distributor.” This definition has apparently left an unintentional loophole for entities servicing nursing home and long-term care patients, which argue that they are not, by definition, a health care entity (not providing diagnostic, medical, surgical, or dental treatment, and not chronic or rehabilitative care) and, therefore, should not be prohibited from selling the discounted pharmaceuticals they purchase. Compounding the problem is the fact that manufacturers are not required to, and often do not, verify that a pharmacy is actually servicing the population they claim to be servicing to receive the discount. These circumstances have lead to some pharmacies, often termed “closed door” pharmacies (since they do no service walk-in patients), reselling discounted pharmaceuticals at a significant profit to secondary source wholesalers who resell them at a significant profit to other secondary source wholesalers, or even to primary wholesalers, who purchase them for less than they can purchase the products from the manufacturers. Experts have estimated that between 50% and 80% of “closed door pharmacies” are participating in these diversion schemes.

Compounding the loss in revenue to manufacturers is a lack of oversight by some manufacturers over the system by which discounts are actually given. Known as a “charge back” system, manufacturers credit wholesalers the negotiated discount upon notification by the wholesaler of a sale to a pharmacy eligible to receive the discount. Apparently, wholesalers have notified manufacturers of sales of products purchased from the secondary wholesalers, not the
manufacturers, and manufacturers have provided credit for such sales. An estimated $1 billion is lost annually due to these activities.

Peg O’Rourke and Pat Durkin of the US Food and Drug Administration (FDA), via conference call, acknowledged the problem outlined by Allen and Macdonald and stated that the FDA is investigating and prosecuting these entities engaged in fraudulent activities using federal wire and mail fraud statutes but lack direct prosecutor authority under the PDMA. It was recognized that many states already have laws and regulations that prohibit pharmacies from reselling prescription drugs to other entities beyond a certain percentage of sales (usually 5%) but that some states lack the resources to investigate and prosecute cases of this nature.

O’Rourke stated that perhaps a solution to the problem, in addition to amending the PDMA to close the loophole, would be the requirement that a drug “pedigree,” a statement identifying each prior sale, purchase, or trade of such drug, be provided to the purchaser of a prescription drug before the completion of any wholesale distribution by any wholesale distributor. Final regulations published on December 3, 1999, and scheduled to become effective October 1, 2001, require a pedigree prior to the distribution of a prescription drug for which the seller is not an “authorized distributor of record” or an “authorized wholesaler,” a distributor with whom a manufacturer has established an ongoing relationship to distribute such manufacturer’s products. Macdonald and Allen commented that if a pedigree were to be required for all wholesale transactions, not just transactions involving unauthorized wholesalers, it would help solve the problem and would also assist in resolving other problems, such as the introduction of counterfeit drug products into the marketplace.

**TFDDIO Recommendation #1**
The Task Force on Drug Diversion through Institutional Outlets recommends that NABP encourage legislative and/or regulatory changes in the PDMA to closer the loopholes that presently exist and are being exploited to allow for activities that are detrimental to the public health. Further, the Task Force recommends that appropriate resources be provided to states and the FDA to ensure that the PDMA is effectively enforced.

**Background:**
The Task Force recognized that the diversion of pharmaceuticals through hospitals and health care entities was one of the primary reasons for the adoption and implementation of the PDMA, and acknowledged that such diversion is continuing through new schemes that take advantage of regulatory loopholes in the PDMA. Members agreed that closing the loopholes should be a priority for Congress and the FDA.

**TFDDIO Recommendation #2**
The Task Force on Drug Diversion through Institutional Outlets recommends NABP assign to the NABP Committee on Law Enforcement and Legislation to amend the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* to combat diversion practices. The Task Force recommends that model language include a 10% limit on sales by pharmacies and wholesalers to wholesalers. It also recommends that state boards of pharmacy review their pharmacy practice acts and regulations to ensure their laws and regulations include such provisions.
Background:
The Task Force felt that such provisions would essentially halt diversion activities by limiting the number of legally allowable transactions.

TFDDIO Recommendation #3
The Task Force on Drug Diversion through Institutional Outlets recommends that NABP assign to the NABP Committee on Law Enforcement and Legislation the development of a pharmacy licensure application and a wholesale distributor application for possible inclusion in the Model Act. Such applications must require applicants to disclose critical data and practice specifics so that the board of pharmacy may determine the legitimacy of applicants’ operations. Applications should obtain detailed information on the following topics:

1. Personal information;
2. Marital information;
3. Family information (parents, siblings, in-laws);
4. Education;
5. Military information;
6. Arrests, detentions, litigations, and arbitrations;
7. Residences (past 25 years);
8. Employment (back to age 18);
9. Character references;
10. Safe deposit box or other depository information;
11. Privileged, occupation, or professional licensure;
12. Out-of-state business, venture or industry or financial interest in such;
13. Appearances before any licensing agency or similar authority in or outside the state;
14. Denials of a personal license, permit, certificate, or registration for a privileged, occupational, or professional activity;
15. Denials of a business or industry license or related finding of suitability, or participation in a group that has been denied a business or industry license or related finding of suitability;
16. Administrative actions or proceedings related to the pharmaceutical industry or participation in a group that has been the subject of such administrative actions or proceedings;
17. Guilty findings or pleadings or pleas of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances or participation in a group that has been found or pled guilty or that has pled nolo contendere to any such offense;
18. Surrender, voluntary or otherwise, of licensure, permit, or certificate of registration relating to the pharmaceutical industry, or participation in a group that has surrendered, voluntary or otherwise, any such licensure, permit, or certificate of registration;
19. Any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry.
Background:
Task Force members based their recommendation on new requirements and policies enacted by the Nevada State Board of Pharmacy to ensure closed door pharmacies are truly pharmacies and not established simply to purchase discounted pharmaceuticals. Careful scrutiny of very detailed and extensive applications by the Board, and a requirement that applicants demonstrate proof that they will be running a pharmacy (provision of actual service contracts), have reduced the number of illegitimate operations in that state.

TFDDIO Recommendation #4
The Task Force on Drug Diversion through Institutional Outlets recommends that NABP encourage states and the FDA to place increased responsibility for the distribution of pharmaceuticals on pharmaceutical manufacturers and authorized wholesalers when distribution patterns are outside what can be considered ethical and reasonable or expected distribution and sale patterns.

Background:
Task Force members felt diversion could be reduced or eliminated if manufacturers were required to monitor the sales of product more responsibly and if wholesalers were required to monitor the appropriateness of sales to “closed door” pharmacies. For example, a wholesaler should question the sale of products that would not normally be used in the population a pharmacy claims to be serving. Members recognized the challenges in identifying abnormal or inappropriate sales but also recognized the benefits of approaching the problem from that perspective.

TFDDIO Recommendation #5
The Task Force on Drug Diversion through Institutional Outlets recommends that NABP survey the states to determine the total number of “closed door” pharmacies presently licensed.

Background:
Members felt that a survey could assist in more accurately determining the extent of diversion and the extent to which boards of pharmacy and NABP should be focusing their efforts on eliminating such diversion.

TFDDIO Recommendation #6
The Task Force on Drug Diversion through Institutional Outlets that all states require all non-resident wholesale distributors to be registered with the state boards of pharmacy if the wholesale distributor ships products into the state.

Background:
Task Force members recognized that the diversion issue extends beyond individual state boarders and that the public would benefit, not only from more state having regulatory control over wholesale distributors but also from the board of pharmacy having regulatory oversight. State boards of pharmacy are the only agency with the regulatory expertise to effectively evaluate the activities of wholesale distributors.
**TFDDIO Recommendation #7**
The Task Force on Drug Diversion through Institutional Outlets recommends that NABP open discussion with other national pharmacy groups about this issue to discuss its impact on the public health. It also recommends that NABP put forth efforts to educate pharmacists, patients, other health care professionals, legislators, and other entities involved in the distribution and dispensing of medications about activities that could be illegal and dangerous to the public health.

**Background:**
Task Force members did not understand why this issue has not been raised by other national pharmacy organizations and insisted that education on this issue be a priority of NABP and the state boards of pharmacy.

**TFDDIO Recommendation #8**
The Task Force on Drug Diversion through Institutional Outlets recommends that NABP begin discussions with the pharmaceutical manufacturers to revise their pricing policies to address the public health issues and eliminate the practices which encourage diversion.

**Background:**
The Task Force recognized that a primary incentive for diversionary practices is the present pricing structure utilized by the pharmaceutical manufacturers. Members recognized the economics of this issue and the impracticality of imposing price controls and restrictions but hoped discussions with the manufacturers could initiate a reevaluation of the appropriateness of multi-tiered pricing and, perhaps, encourage the distribution of costs throughout the entire system.