



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

Before the Senate Committee on Commerce, Science and Transportation

Hearing on:

“Short Supply Prescription Drugs: Shining a Light on the Gray Market”

July 25, 2012

Testimony of Virginia Herold

Executive Officer

California State Board of Pharmacy

Dear Chairman Rockefeller, Ranking Member Hutchison and Committee Members:

Good Afternoon.

I am Virginia Herold, Executive Officer of the California State Board of Pharmacy. It is a privilege to be given this opportunity to address the committee on California's efforts to address some of the unethical and illegal behavior surrounding manipulation of prescription drug shortages by wholesalers and pharmacies, to the detriment of the public health. As I speak today, our investigations and resultant enforcement activities that I describe below are not yet fully completed.

The California State Board of Pharmacy licenses pharmacies, pharmacists, drug wholesalers and other entities that dispense, ship, transport or store prescription drugs and devices into, throughout and from California. The board is the largest licensor of pharmacies and pharmacists in the country – nearly 40,000 pharmacists, 6,200 community pharmacies and 500 wholesalers are located in California and licensed by the board. The board's paramount mandate, which is expressly stated in the California Business and Professions Code, is consumer protection.

California state law provides the limited circumstances under which a pharmacy may provide prescription drugs to any entity. One of the provisions provides that a pharmacy may furnish prescription drugs to another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous (or prescription) drug that could result in the denial of health care and only in

quantities sufficient to alleviate the temporary shortage. Violations can be charged up to \$5,000 per occurrence (e.g., invoice). A copy of this code section is provided as an attachment to this testimony.

In the fall of 2011, the board initiated an investigation following a pharmacist's inquiry about the legality of the pharmacy ordering prescription drugs in short supply from its primary wholesaler, expressly for sale to another wholesaler. These sales would be initiated at the behest and solicitation of the second wholesaler, who informed the pharmacy that the prescription drugs were declared as temporarily short and thus these sales were legal.

The pharmacy's role would be to act as a purchasing agent for the wholesaler, purchasing drugs specifically on a list of prescription drugs in short supply that the wholesaler provided to the pharmacy. The arrangement between the pharmacy and wholesaler was financial: the pharmacy would be paid an agreed amount, typically 10 percent over invoice, plus shipping expenses.

The board initiated an investigation of the California wholesaler making this solicitation, which yielded hundreds of invoices from 55 California pharmacies that had sold prescription drugs in short supply to this wholesaler, at the wholesaler's request. The board next investigated each of the 55 pharmacies, interviewing the pharmacists-in-charge or others who had knowledge of the sales. Again, invoices were obtained from each pharmacy.

As of today, the board has identified cases in which 55 pharmacies purchased drugs in short supply for the wholesaler on 514 occasions, totaling wholesale prices of over \$330,000. Each of

the pharmacies and their pharmacist-in-charge have been cited and fined in various amounts up to \$70,000 for violation of California law. Appeals of these citations and fines are currently pending. The wholesaler has not yet had discipline completed. Thus none of these actions and investigations is fully concluded. However, we are sharing this information to the committee in hopes of securing enhanced ways to stop the practices identified by the board.

The board's investigations generally identified that:

1. A pharmacy would be visited by a sales agent/representative of the wholesaler, who explained the dire impact that drug shortages presented to patients and health care providers, and stressed the inability of the wholesaler to obtain these drugs on its own. This soliciting wholesaler advised that it was another source of pharmaceuticals for medical facilities, and needed these medications.
2. Sales were triggered from a list the wholesaler released each week to the pharmacies titled "Items we are looking for."
3. The pharmacies involved were all independent, community pharmacies.
4. The drugs were principally medication that that would be used by hospitals and rarely would be needed by community pharmacies. The board did not find cases where the pharmacies purchased drugs for their own patients needs – all drugs were purchased exclusively for the wholesaler using the list.
5. The pharmacies had no independent knowledge of the shortage.
6. Some of the pharmacies seemingly circumvented the allocation system set up by manufacturers by making multiple orders on the same day at different times. For example, one pharmacy ordered acetylcysteine 12 times in one day to maximize the

amount purchased. Other times, large orders were made (30 boxes of 25 vials of magnesium sulfate).

7. Pharmacies were typically paid 10 percent over invoice for the drugs they purchased for the wholesaler.
8. However, the wholesaler also sought direct access to the pharmacies' primary wholesaler ordering systems, which was granted by 23 pharmacies -- allowing the wholesaler to directly order the drugs it sought without the active involvement of the pharmacy. For this access, typically the pharmacy was paid 12 to 15 percent over invoice.
9. Several pharmacies also sold drugs in short supply to other several other wholesalers, including several wholesalers out of California who were not licensed to do business in the state.

The wholesaler made considerably more when it resold the short supply prescription drug than the 10 to 15 percent it paid the pharmacy. Some of the extreme examples include:

1. Labetalol sold to a Naval hospital: 6,246 percent markup.
2. Leucovorin sold to a hospital: 996 percent markup.
3. Famotidine sold to a hospital in Georgia: 1240 percent markup.
4. Calcium gluconate sold to a hospital in Los Angeles: 441 percent markup.

The wholesaler also resold about 10 percent of the short supply drugs it had purchased to other wholesalers, not to pharmacies or health care providers. These wholesalers were charged lower fees (e.g., sometimes 40 percent over the price paid by the wholesaler). The board also

documented cases where the wholesaler resold the entire quantity purchased to another wholesaler.

The board moved forward with these cases because instead of alleviating the shortage of these drugs, the wholesaler instead removed more drug from availability in the legitimate supply chain, which had allocations in place to most equitably distribute the product. We believe that it increased the shortage of the drugs and dramatically increased the cost of these drugs to other health care entities, and thus to patients.

This concludes my statement. Thank you again for this opportunity.

Attachment of Section 4126.5, California Business and Professions Code

- 4126.5.** (a) A pharmacy may furnish dangerous drugs only to the following:
- (1) A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired.
 - (2) The pharmaceutical manufacturer from whom the dangerous drug was acquired.
 - (3) A licensed wholesaler acting as a reverse distributor.
 - (4) Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.
 - (5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law.
 - (6) A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs.
 - (7) To another pharmacy under common control.
- (b) Notwithstanding any other provision of law, a violation of this section may subject the person or persons who committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence pursuant to a citation issued by the board.
- (c) Amounts due from any person under this section on or after January 1, 2005, shall be offset as provided under Section 12419.5 of the Government **Code**. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.
- (d) For purposes of this section, "common control" means the power to direct or cause the direction of the management and policies of another person whether by ownership, by voting rights, by contract, or by other means.