

# WALSH HealthCare Solutions, Inc.

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January 8, 2001

Ms. Jane A. Axelrad  
Associate Director for Policy  
Center for Drug Evaluation and Research  
5600 Fishers Lane, HFD-5  
Rockville, MD 20857

Dear Ms. Axelrad:

I am writing you at the request of Ms. Dianne Goyette to respond to a number of questions that you posed to her by letter of previous date. The company I represent, Walsh HealthCare Solutions, manages four warehouse operations located in Texas, Arkansas and Alabama serving the south and southeast regions of the country. Combined sales for the four facilities are in excess of 1.5 billion dollars per year – making Walsh the seventh largest drug wholesaler in the country.

After review of the five questions that you have posed to the five primary wholesalers, my initial response is to direct your attention to two letters prepared by Ms. Goyette, both of which are addressed to the Dockets Management Branch (HFA-305) and dated July 3, 2000 and November 20, 2000 respectively. Both letters clearly and accurately address the concerns that the wholesale industry has with the regulations currently being proposed by the Agency to implement the Prescription Drug Marketing Act (as the Act relates to the regulation of the secondary wholesaler market). Both letters accurately represent Walsh's concerns as well.

However, where I am able, I will attempt to elaborate on the concerns set forth in Ms. Goyette's letters in response to your specific questions.

- 1. At the Agency's Part 15 Hearing on October 27, 2000, we heard representatives of wholesalers of prescription drugs say that the largest wholesalers would oppose the requirement of a universal pedigree. Please state whether you would favor or oppose such a requirement and why.**

Walsh would oppose such a requirement. Please see Ms. Goyette's letter of November 20<sup>th</sup>. Therein she describes in Section IV the burdens these regulations would place upon wholesalers due to the number of items and sheer volume of product being handled on a daily basis. Furthermore, the consensus among Walsh personnel is that warehouse operations for every facility would have to be drastically restructured to accommodate the requirement of a universal pedigree – rather than receive, stock and otherwise track product by manufacturer and NDC number, each product received into the warehouse must be tracked by lot number as well. Tracking products by lot number represents a *significant* change in the way Walsh currently operates; and therefore, Walsh can expect to incur substantial costs in order to implement the requirement of a universal pedigree.

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2. **We understand that there are computer software and systems readily available that can be used to create a pedigree. What do you believe it would cost to create a pedigree and provide it with the drugs that you sell?**

As Ms Goyette noted in her letter of November 20<sup>th</sup>, the cost to create a pedigree software program is uncertain. However, there are no known software programs currently used by Walsh that could be easily adapted to create a pedigree. And, as I have indicated above, warehouse operations would also be restructured. Therefore, the costs to develop software, hardware and warehouse processes to accommodate a universal pedigree can be expected to be tremendous.

**What would these costs be associated with specifically?**

Factors that must be considered to develop effective software program and warehouse processes include:

- Rewriting all current software programs as well as the need to revise all paper forms, including invoices, shipping manifests, debit and credit memos, and the like to provide for the tracking of product by lot number;
- To eliminate the need for manual data entry of data when product is received at the warehouse, developing software programs that can electronically transmit data from one distribution point to the next will be required; and
- Restocking and/or relabeling all product stored in the warehouse facilities.

**Do you believe these costs could be accommodated without a significant increase in the cost or decrease in the availability of prescription drugs?**

No. Profit margins in the wholesale industry are less than 1 percent. Therefore, it would be difficult to foresee the industry being able to absorb the additional costs that are incurred to implement a universal requirement for a pedigree. Rather, the costs would necessarily be passed on to our customers and ultimately on to the consumer.

3. **Do you believe it would be advisable to eliminate the pedigree requirement altogether? Please explain your answer.**

No -- the pedigree requirement should remain in its present form, i.e. requiring secondary wholesalers to provide a pedigree back to an authorized distributor or the manufacturer. Because a secondary wholesaler is indicative of a wholesaler who has not established an ongoing business relationship with a manufacturer, the ability of authorized distributors to be able to identify the sources that product was purchased is invaluable. With the pedigree information provided by secondary wholesalers, authorized distributors are able to make purchasing decisions based in part upon whether a particular point in the distribution channel has handled and stored product in conformity with PDMA regulations.

4. **Do you believe there would be any consequences to the public health and safety of the pedigree were eliminated?**

Possibly. When an authorized distributor purchases product directly from the manufacturer, the ability to retrace the chain of distribution back to the manufacturer, and therefore, who, when and how the product was handled and stored, remains a relatively simple task. However, when

product is purchased from secondary wholesalers, and therefore, additional points of distribution are added to the chain, the ability to retrace the steps the product followed along the chain of distribution can become quite complex. Without the current pedigree requirements for secondary wholesalers (providing a pedigree back to an authorized distributor or the manufacturer) the ability to retrace the distribution channel may prove to be impossible. And without the ability to retrace the chain of distribution for a given product, authorities may be unable to discover the source, or identify reasons, which have contributed to a product's having been determined to be dangerous for consumption by the public.

5. **What would your position be on the following requirement?**

**All distributors (authorized and unauthorized) must maintain and pass on a pedigree for those prescription drugs that are bought from or sold to a secondary distributor.**

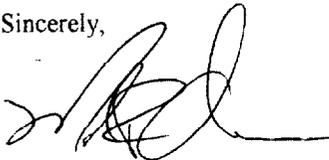
Walsh is opposed to this requirement. Although the application of the pedigree requirements would be limited to transactions involving secondary wholesalers, the need to develop software programs and warehouse processes to comply with the requirements of tracking product by lot number continues. Therefore, Walsh would again be forced to rewrite all software programs, and revise all shipping documents to accommodate lot number tracking.

Further, lot number tracking would necessarily be required for all products handled and stored in the Walsh facilities. Otherwise, each facility would be forced to maintain dual inventories and the efficiencies currently realized in warehouse operations (and passed on to our customers in terms of lower prices) would be lost.

I appreciate your, and the agency's, time and careful consideration that has been given to this matter. While I may have been brief in my responses, I trust that this information, together with Ms. Goyette's letters of July 3<sup>rd</sup> and November 20<sup>th</sup>, will provide you with a better understanding of the concerns Walsh has with the proposed pedigree requirements.

If I can be of further assistance, please feel free to contact me at (903) 255-2301.

Sincerely,



Mark R. Adams  
Vice President & General Counsel

cc: Ms. Diane Goyette, Director of Regulatory Affairs  
Mr. Randy Wilson, Vice President, Inventory Management