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Background

Of the 55 novel drug approvals in 2023, 28 (51%) were identified by the Center for Drug Evaluation and Research (CDER) as having been granted orphan drug designation to treat rare diseases, and 15 (54%) of the orphan therapies approved are cold chain products.¹

Temperature sensitivity represents one of the most significant challenges in shipping cold chain medications. Maintaining temperature control during transportation is essential to preserve medication integrity throughout the supply chain and ensure safe delivery to patients.² Cold chain products require more effort and packaging materials compared to ambient temperature products, presenting unique challenges for specialty pharmacies when it comes to ensuring safe medication delivery while minimizing environmental impact.

Health Care Without Harm, an international non-governmental organization (NGO), estimates that the health care sector contributes 4.4% of global carbon emissions. Scope 3 emissions, which are primarily derived from the health care supply chain, account for 71% of emissions within the sector.³ Pharmacies can reduce their carbon footprint and improve cost-efficiency through sustainable business practices including the selection of eco-friendly packaging materials and the implementation of container recycling programs. However, the environmental and financial impact of such programs in specialty pharmacy has not previously been quantified and reported.

Objective

To assess the impact of an automated cooler return program on environmental sustainability, costs, and patient perspectives related to shipping of cold chain medications within a national rare disease pharmacy.

Methods

This retrospective analysis utilized a national rare pharmacy database to identify all patients eligible for participation in an automated cooler return program based on therapy type and shipping carrier between August 1, 2024 and January 31, 2025 (n=3912).

Cooler returns were quantified utilizing logistics partner invoices for return services, and the environmental impact of the automated cooler return program was evaluated via estimation of landfill volume saved through the reuse and recycling of returned coolers and ancillary cooler supplies.

The financial impact of the enhanced cooler return service model was assessed as a percentage of material cost savings, calculated using material costs associated with returned and reconditioned coolers, phase change materials (PCMs), and gel packs compared to the projected material costs associated with a single-use pack out model for all shipments of qualifying therapies over the 6-month period.

Patient perceptions were assessed using a one-time telephonic survey offered to all patients participating in the automated cooler return program.

Results

Table 1. Participation in Automated Cooler Return Program Amongst Eligible Patients

Initial Status	Total (n=3,912)	Most Recent Status		
		Patient opts-in	Patient opts-out of entire program	Patient opts-out this fill
Patient opts-in	3461	3594	220	98
Patient opts-out of entire program	99	3311	110	40
Patient opts-out this fill	352	33	64	2
		250	46	56

Table 2. Estimated Landfill Volume Saved by Cooler Returns

Program	Return Shipment Count	Estimated Landfill Volume Saved
Therapy #1	6,062	12,460,145.33 in. ³
Therapy #2	1,236	5,944,675.884 in. ³
Therapy #3	3,549	4,982,701.455 in. ³
Therapy #4	2,506	1,750,815.898 – 12,052,878.45 in. ³
Overall	13,353	25,138,338.56 – 35,440,401.11 in. ³

Figure 2. Landfill Volume Point of Reference
Annualized estimated landfill volume saved through the reuse and recycling of returned coolers is equivalent to that of 8.07 to 11.0 fully packed standard 53-foot tractor trailers.

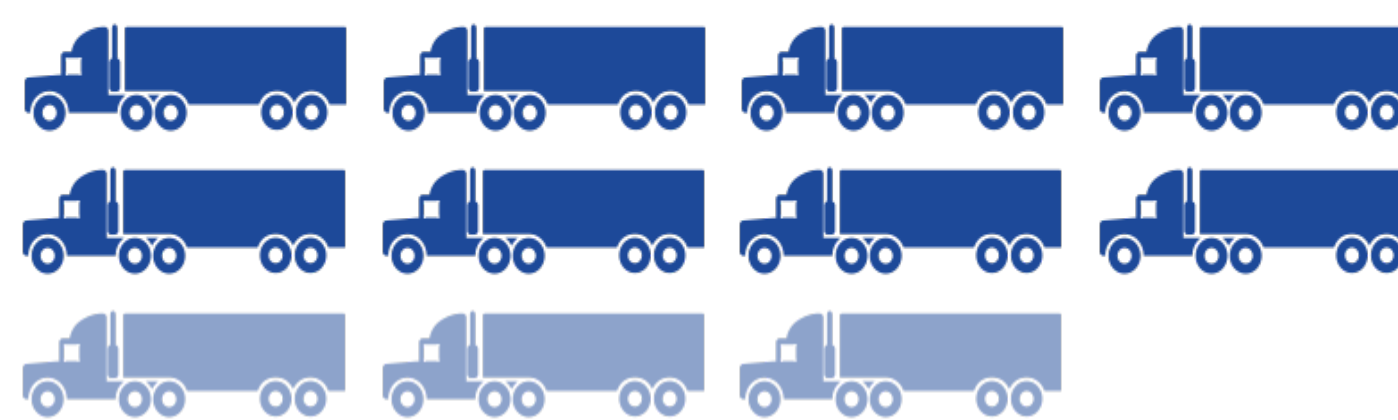


Figure 3. Patient Reported Overall Satisfaction With Automated Cooler Return Program

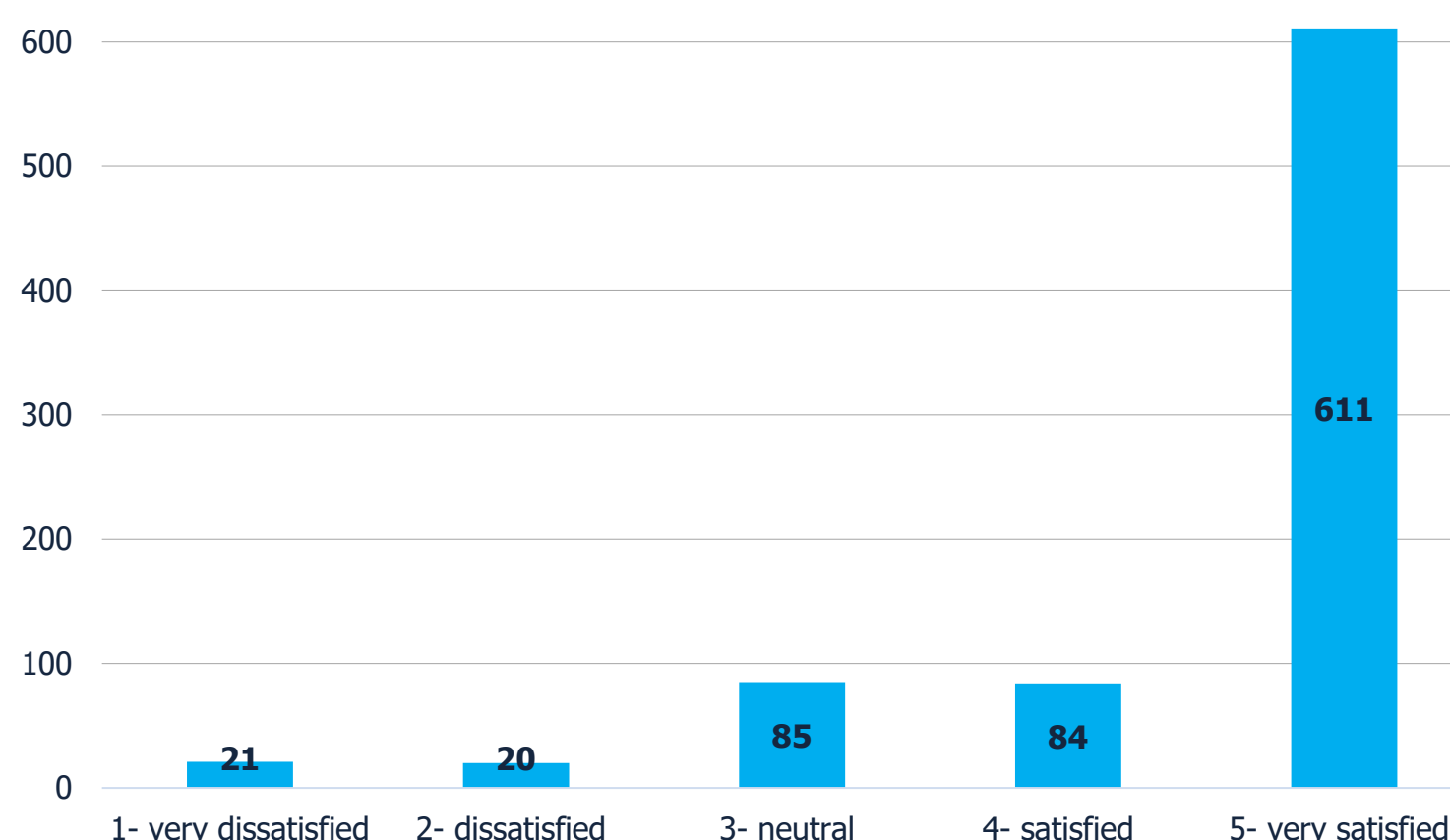


Figure 1. Cooler Return Rate

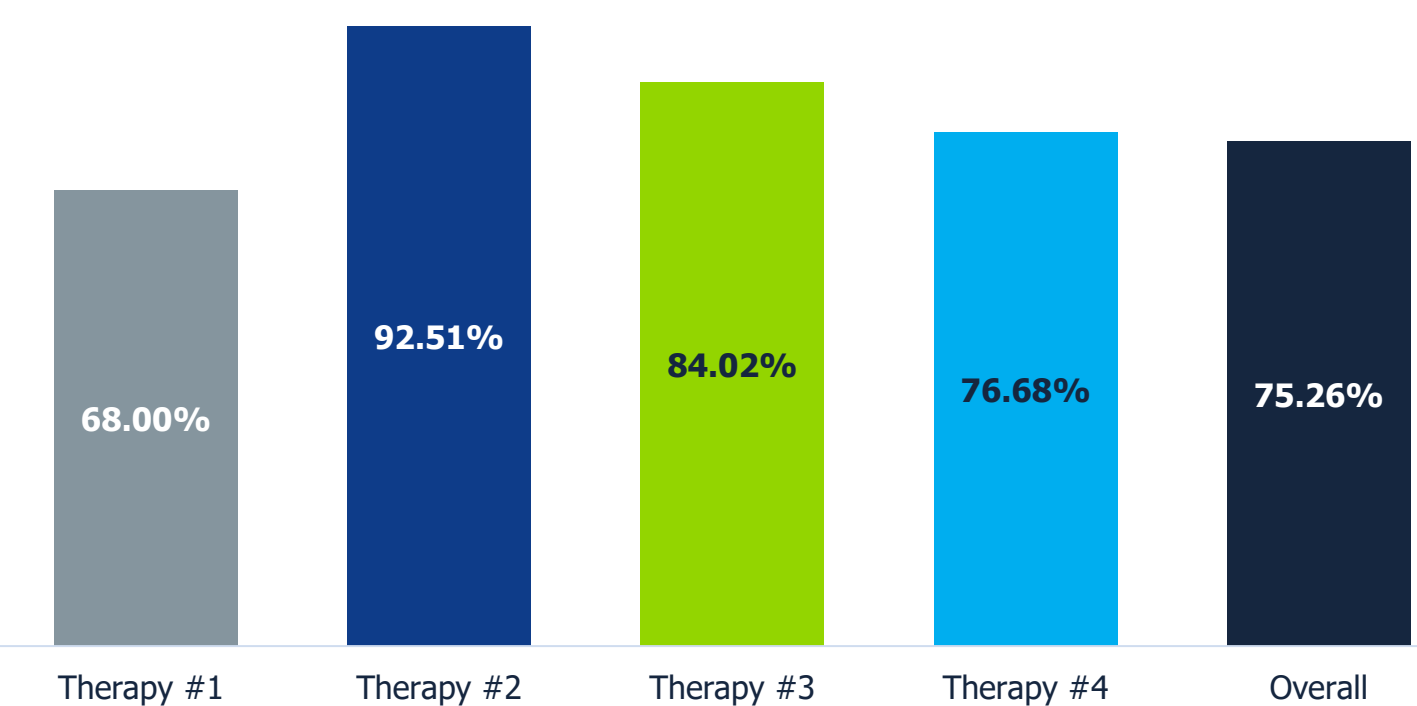
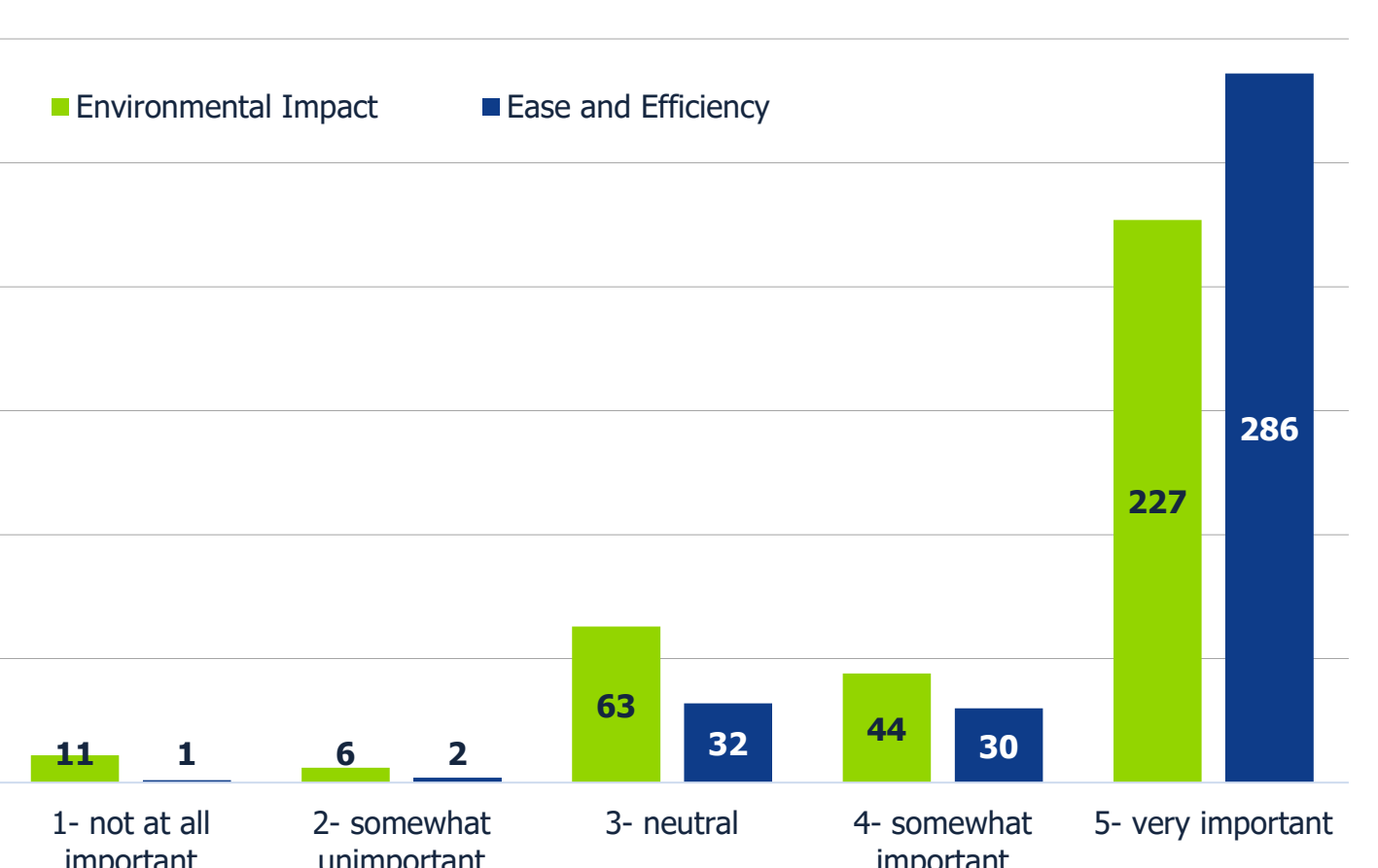


Table 3. Estimated Material Cost Savings

Overall Estimated Material Cost Savings 66%	
Therapy #1	64
Therapy #2	87
Therapy #3	74
Therapy #4	66 – 72

Figure 4. Patient Reported Importance of Environmental Impact and Ease and Efficiency of Automated Cooler Return Program



Discussion

This 6-month retrospective analysis identified 3,912 patients across four cold chain therapies eligible for the automated cooler return program. Participation was high, with 3,461 (88%) patients opting in at the time of initial offer and 3,594 (92%) by the conclusion of the study. Of the 352 patients who initially opted out for their first eligible shipment, 250 (71%) later chose to participate, suggesting a potential hesitancy due to the program's novelty. Cancellation rates were low, with 3,311 (96%) patients remaining in the program throughout the research period (Table 1).

A total of 13,353 (75.26%) coolers were returned, saving an estimated 25,138,338.56 to 35,440,401.11 cubic inches of landfill space (Table 2, Figure 2). Furthermore, an estimated 66% overall material cost savings was assessed for the returned coolers, PCMs, and gel packs as compared to single-use material cost projections (Table 3).

Patient survey results indicated that 611 (74%) respondents were 'very satisfied' with the automated cooler return program overall (Figure 3). While both environmental impact and efficiency were rated highly, patients ultimately placed greater value on ease and efficiency, which may be attributable to its direct impact on patient experience (Figure 4).

The results of this study have several limitations. Study duration was limited by the recent implementation of the automated cooler return program. Additionally, due to the inability to tie returned coolers and ancillary supplies to patient-specific shipments, we were unable to determine the exact ratio of pack out type used for therapies with variable pack outs based on factors such as shipment date, delivery location, and patient preference. Therefore, landfill volume and material cost savings estimate ranges are reported based on the assumption that all patients received one type or the other. Lastly, the patient survey population was limited, as an existing survey was adapted to assess patient perspectives on the environmental impact and ease and efficiency of the program.

Conclusion

This initial 6-month analysis of an automated cooler return program within a national rare disease pharmacy demonstrates that specialty pharmacy container recycling programs can reduce both carbon footprint and costs while improving patient experience. While this study was limited in its duration and scope, the results highlight the potential for positive impact of such programs for patients, pharmacies, and the planet alike. Future research should be conducted to expand these results over a longer period of time and examine additional factors including the life cycle of reusable packaging materials.

References

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