THINK INSIDE THE BOX:
How to Reduce Costs of Specialty Pharmaceutical Shipments and Increase Patient Satisfaction

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Summary:
The specialty pharmacy industry could reduce costs by $27.5 million annually (product and call center staff costs only) if visual temperature indicators were used as decision-making tools to determine if medicine should be used or returned when patients suspect heat damage. In addition, 97% of patients surveyed, who received medicine from specialty pharmacies with a visual temperature indicator included in the package, agree that they would want an indicator in all shipments and 95% agree the indicator increased their confidence in the medicines received.

Overview:
This paper presents findings from a consumer research study examining the preferences and insights of patients with chronic disease who receive temperature-sensitive medicines through specialty pharmacies.

Specialty pharmacies were once considered niche businesses in a retail-dominated industry, but today the sector is a dominant force. The specialty pharmacy business model supports patients with serious, chronic conditions and complex disease states like rheumatoid arthritis, multiple sclerosis, psoriasis, and Crohn’s disease. They do so through a broad range of high-touch services -- patient assistance, compliance/persistence, and educational counseling programs – as well as through management and distribution of high-cost specialty medicines not available through retail pharmacies.

These “specialty drugs” are significantly more expensive than traditional pharmaceuticals. The average cost for a specialty prescription is more than $3,000, while some cost as much as $50,000 for a 30-day supply. Moreover, they now represent an increasing piece of total insured drug sales and today, specialty drug expenses amount to 33.4% of total (pharmacy and medical) drug costs. If current trends continue, experts predict that specialty drugs will represent more than 50% of total drug costs by 2018.

Most specialty drugs are biologics, requiring special storage and handling conditions to maintain a specific temperature range, usually 2°C to 8°C. These shipping and handling standards are in place to protect the drugs from exposure to temperature excursions beyond the acceptable range, which may damage or destroy them.

Biologics are affected by excessive heat or cold and exposure to extreme temperatures can result in reduced potency, which cannot be restored. If the cold chain is not properly maintained, in time, the agent will become completely ineffective. If temperature damaged medicine is administered, there may be serious downstream effects: patients may experience diminished symptom control, interruptions in treatment protocol, additional physician visits, change in prescribed medicine, and in the case of vaccines, reduced or no protection from preventable diseases.

In order to maintain the recommended temperature range and safeguard against potentially damaging excursions, specialty pharmacies ship medicines to patients in specifically designed insulated thermal boxes.

However, results of a recent independent study showed that none of the thermal packaging systems tested that are typically used by specialty pharmacies to protect temperature-sensitive products for direct-to-patient delivery, maintained the specified temperature in the first 24 hours. All packaging tested performed below expectations when tested to the ISTA 7D industry standard. Most did not perform against their own published claims. The results of this study point to a need for additional monitoring during transit, particularly during the “last mile” when medicines are delivered late by the carrier or when there are delays by patients in opening and properly storing their medicine.

Our team understands that certain specialty medications require specific storage conditions when being shipped to our patients. Without proper temperature controlled surroundings, prescription drugs may be compromised, possibly affecting their potency and rendering them unsafe to use.

Jonathan VanLare, PharmD, RPh
Manager, Clinical Service, Pharmacy Advantage
It is virtually impossible to discern by visual examination if biologic medicines are temperature damaged, which is why indicators that alert to temperature breaches are very useful in verifying whether the recommended temperature range has been maintained. Further, they streamline costs associated with medication returned by patients concerned about the temperature of their shipments, and mitigate potential health risks if damaged medicines are injected.

Specialty pharmacies serve as the first touch-point for customers who suspect their medicine may have been exposed to excessive temperatures. The standard process is for customer service representatives to guide callers through a telephone evaluation to determine whether the medicine should be used or not. Without a definitive monitoring tool, however, the decision is based on conjecture.

Cost is a key factor when product is “wasted” – or, discarded when it could have been used. Replacing and reshipping high-value biopharmaceuticals is expensive, as is the cost of staffing and managing customer service centers to handle patient inquiries. Cost is also a consideration when patients administer damaged product because this opens up the possibility of negative health outcomes. In all cases, the absence of a scientific monitoring tool elevates patient risk and increases the cost of disease management.

The issue stretches beyond patients and specialty pharmacies. Payers have a major stake in the healthcare outcomes of their members. They rely on the experience and infrastructure of specialty pharmacies for comprehensive medication management, and they are growing increasingly concerned about the rising costs of biologics and investing heavily in ways to control utilization and costs.

Pharmaceutical manufacturers, too, have a vested interest in optimal clinical outcomes, streamlined customer service processes (patients also contact manufacturers with concerns about medicine temperature) and ensuring optimal patient care.

In 2012, based on discussions with a national sampling of specialty pharmacies, an on-going product-in-use study was fielded to examine patients’ experiences and concerns about the temperature of medicine shipments upon delivery, their attitudes about temperature indicators, and preference for indicator use. Cost impact to specialty pharmacies during the test period was also reported.

**Objectives:**

- Learn patient experiences and attitudes about temperature-sensitive medicines received through the mail
- Assess patient ease of understanding instructions, and reading TransTracker® F visual heat indicators
- Assess patient interest in the value of a temperature monitoring device packed with medicine shipments
- Assess cost benefits to specialty pharmacies regarding the use of temperature indicators in every shipment of biopharmaceuticals to patients

**Study Methodology:**

- Five (5) specialty pharmacies agreed to include the following materials in regular shipments to patients:
  - Letter from the specialty pharmacy
  - TransTracker® F visual heat indicator, a single-use device that monitors temperature exposures during shipping and signals to show when a specific temperature has been exceeded for a defined time period
  - Instructions on how to read TransTracker® F
  - A survey with instructions on how to respond
- Specialty pharmacies from the Northeast, Southeast, Midwest, Western regions participated
- n = 5,967 patient responses received (YTD 12/31/13)
- Patients could respond on-line or complete printed surveys and return via Business Reply Mail to an independent researcher
- Responses were entered into a database for consolidation and analysis

The study began in 2012 and results are reported through 12/31/13.
**Results:**

The study found that patients with chronic conditions have direct experience with the uncertainty about whether or not shipments received have been maintained within proper temperature range. Almost half of respondents (49%) indicated they’ve been concerned that the temperature of medicine received from a specialty pharmacy was too warm or too cold. (Figure 1) An even greater proportion of respondents (60%) reported being concerned about heat damage. (Figure 2)

Patient confidence in their medicine increases when a temperature indicator is included in each shipment. More than 95% of patients agree that a temperature indicator included with shipments would increase their confidence in the medicines from that company. (Figure 3)

More than 95% of patients agree that a company that includes visual indicators with each shipment of medicines to patients shows a concern for their safety. (Figure 4) and that if given the choice, 89% would choose to receive medicine from a company that includes a visual temperature indicator in every shipment versus a company that did not. (Figure 5) An overwhelming majority of patients – 97% – want the company that sends medicine to them to include a TransTracker® F temperature indicator in the box whenever medicines are shipped to them. (Figure 6)

Nearly all patients in the study agree that the monitoring device instructions are easy to understand (98%) and the temperature indicator is easy to read (98%). (Figure 7) Most patients (93%) noticed the TransTracker® F indicator card in the shipment box, and 96% read the instruction sheet “How to Use the TransTracker® F Indicator Card” on the back page of the customer letter.

A small percentage (<2%) of the indicators were reported to have signaled during the study period. (Figure 9)

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**Specialty Pharmacies:**
**Visual Indicators Lower Costs**

In addition to distributing patient surveys, select participating specialty pharmacies reported cost advantages directly attributed to the use of TransTracker® F visual indicators.

One specialty pharmacy conducted an assessment of shipments of a single biologic two months prior to the start of the study compared to the first two months of the study period when a TransTracker was included in every shipment of medicine to patients. Results show a 70% reduction in product waste alone. In addition, when savings were projected to include the cost for professional staff to handle patients’ concerns about suspected temperature damage of their medicines, and return/replace/reshipment of the medications, an additional savings of more than $50,000 was realized. Considering the cost of TransTracker and the product and call center dollar savings, the ROI for this specialty pharmacy proved that for every $1 spent to include TransTracker in shipments to patients, $7.50 was saved.

Projected industry wide, the specialty pharmacy industry could reduce costs by $27.5 million annually (product and call center staff costs only) if visual temperature indicators were used as decision-making tools to determine if medicine should be used or wasted when patients suspect heat damage.

Another pharmacy reported saving high-cost medicines suspected of potential heat damage that would have otherwise been discarded. Over six weeks and 850 shipments, two patients called with concerns that their medicine felt too warm, and in both cases, TransTracker® F had not signaled to show temperature excursions above the limit. The pharmacy concluded that without the indicator, the medicine would have been returned and replaced at a cost of approximately $9,200 (product cost only).

A third participating pharmacy analyzed the average time per call spent with patients concerned about the temperature of their medicine delivery and compared the results before and during the study period. Call duration decreased from 9-12 minutes to 4-5 minutes per call during the study period, a reduction of approximately 50%.
Discussion:
The high cost of specialty pharmaceuticals, coupled with a pattern of concern among public health officials, physicians and patients about temperature compromised medications, has spurred specialty pharmacies to look at ways to mitigate risk to patients, contain shipping costs, and ensure a high quality standard of patient care.

One approach tested by specialty pharmacies — including a visual temperature indicator in every direct-to-patient shipment — strengthened the quality care processes already in place in the specialty pharmacy setting, thereby reducing costs and increasing the satisfaction of high-value patients.

Temperature Indicators Reduce Waste, Costs, and Time

Visual temperature indicators like the TransTracker® F (Figure 10) have been proven to address gaps in the pharmaceutical cold chain and are extremely useful during the “last mile.”

In the direct-to-patient setting, a simple “Use” or “Don’t Use” reading allows patients and specialty pharmacy personnel to make informed decisions about whether or not to use the medicine — in half the time. An objective reading from a science based temperature indicator enhances patient confidence in the decision-making process. It supports optimal clinical outcomes and reduces overall cost of care associated with return/replacement of medicine suspected to be damaged by excessive temperature exposure.

The cost of a chronically ill patient inadvertently administering heat-damaged biopharmaceutical medicine can be significant. There may be gaps in an established treatment regimen, changes in medication, adverse events, and even a hospitalization — which can cost tens of thousands of dollars per day. Regardless of the specific negative health effect(s), the consequences of administering temperature-damaged medicine can contribute to poor outcomes and higher healthcare costs.

Specialty pharmacies staff their customer service call centers with trained professionals who field calls from patients concerned about their medicine. Using indicators as the definitive tool to determine whether to use the medicine can effectively streamline the call center operation by reducing the number of calls and the professional time spent on each call.

Patient Satisfaction

The research findings are particularly important to specialty pharmacies placing high value on customer satisfaction and meeting the needs of patients who rely on them to deliver life-saving medicines to their doorsteps. The decision to ship with indicators could enhance a specialty pharmacy’s standing among high-value patients and foster loyalty from patients who may remain customers for years.

The carrier from the Post Office brought my insulin at 9:00pm and said she almost didn’t deliver it because it was covered up…in the truck. The FIRST thing I did was to check the temperature indicator. Thanks!

DK, patient
Jackson, MI

My wife and I had this very concern about medication temperature during the warm summer months when a delivery came and the cold packs were all under the medication. When I measured the temperature between the lid and the medication I read about 70 degrees. After contacting the pharmacy, they determined that the medication was okay due to the short duration of the temperature excursion. With this TransTracker F indicator, I would have felt far more confident. The concerns I had about temperature are completely addressed now.

CP, patient
Pine Brook, NJ
**An Improved Quality Standard**

Specialty pharmacies choosing to include indicators in shipments are taking a major step toward improving quality processes and fulfilling their mission of keeping patients at the center of care.

Temperature monitoring devices close well-documented gaps in the pharmaceutical cold chain by eliminating uncertainty about whether a medicine has been exposed to temperature outside specified limits. The additional layer of quality control to specialty pharmacy medical utilization and management processes plays a key role in containing costs and enhancing clinical outcomes.

Manufacturers and payers, who partner with specialty pharmacies for their expertise in comprehensive medication management, continue to focus with increasing intensity on positive clinical outcomes and patient-centric care. These stakeholders should consider temperature indicators as a layer of added value specialty pharmacies can provide to protect product assets and safeguard patient care.

The hallmark of a well-designed cold chain is a reliable visual temperature indicator included in every shipment. Specialty pharmacies have found that when integrated into the cold chain shipping process, these tools benefit all medical management stakeholders – pharmacy, manufacturer, payer, and patient – by lowering costs and supporting the best standard of care for patients.

**Conclusion:**

The data show that temperature indicators are useful to specialty pharmacies and their patients as a definitive tool to determine if medicines have been exposed to heat above a specific limit during transit.

The data also illustrates that patients are concerned about heat damage that occurs during transit and delivery. The presence of an indicator in each shipment enhances their confidence in the medicine received from specialty pharmacies. They believe strongly that companies choosing to include temperature indicators are concerned about patient safety, and express a clear preference for specialty pharmacies that include indicators.

By incorporating indicators into the cold chain shipping process, specialty pharmacies are responding to the needs and preferences of their customers, and realizing cost advantages in the form of reductions in product waste, replacement and reshipping costs, and benefits from streamlined call center operations.

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*By shipping with visual temperature indicators, our pharmacy provides another level of quality assurance to our partnership with payors. Patients are taken care of the first time around, and the costs of managing direct-to-patient shipments – indicators, product returns and replacements – are minimal as compared with a potential inpatient hospitalization from administration of heat-damaged product or a gap in therapy.*

*Dan Kus, RPh*

*Pharmacy Advantage*
Figure 1. Specialty Pharmacy Patients Are Concerned About the Temperature of Their Medicine When it Arrives

Have you ever been concerned medicines sent were too warm or too cold?

- YES: 51%
- NO: 49%

Figure 2. Patients Are Concerned That Their Medicine May Become Heat Damaged During Transit

I am concerned about heat damage to my medicine.

- Strongly Agree/Agree: 60.4%
- Neither Agree nor Disagree: 12.8%
- Strongly Disagree/Disagree: 26.8%
Figure 3. Patient Confidence in Their Medicines Increases When Shipments Include a Temperature Indicator

A company that includes a temperature indicator with shipments of medicine to me would increase my confidence in medicines I get from that company.

- Strongly Agree/Agree: 95.6%
- Neither Agree nor Disagree: 3.8%
- Strongly Disagree/Disagree: 0.6%

Figure 4. Patients Agree That Specialty Pharmacies That Include Visual Temperature Indicators in Shipments Show Concern for Patient Safety

A company that includes a temperature indicator with shipments of medicine shows concern for my safety.

- Strongly Agree/Agree: 95.6%
- Neither Agree nor Disagree: 2.9%
- Strongly Disagree/Disagree: 1.5%
Figure 5. High Value Patients Have a Strong Preference for Specialty Pharmacies that Include Temperature Indicators Over Those that Do Not

If I could get my medicine from a company that included a TransTracker®F in the box with my medicine vs a company that didn’t include a temperature indicator, I would choose to get my medicines from the company that included the TransTracker®F.

<table>
<thead>
<tr>
<th>Option</th>
<th>Percentage</th>
</tr>
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<tbody>
<tr>
<td>Strongly Agree/Agree</td>
<td>89.3%</td>
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<tr>
<td>Neither Agree nor Disagree</td>
<td>9.9%</td>
</tr>
<tr>
<td>Strongly Disagree/Disagree</td>
<td>1.0%</td>
</tr>
</tbody>
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Figure 6. Almost 98% of Patients Want a TransTracker®F Temperature Indicator Included Whenever Medicines Are Shipped to Them

I want the company that sends medicine to me to include a TransTracker®F temperature indicator in the box whenever medicines are shipped to me.

- YES: 97.8%
- NO: 2.2%
Figure 7. The TransTracker® Instruction Sheet Is Easy for Patients to Understand

The instruction sheet How to Use TransTracker®F was easy to understand.

- Strongly Agree/Agree: 98.3%
- Neither Agree nor Disagree: 1.4%
- Strongly Disagree/Disagree: 0.3%

Figure 8. Patients Found the TransTracker®F Visual Indicator Easy to Read

The TransTracker®F is easy to read.

- Strongly Agree/Agree: 97.9%
- Neither Agree nor Disagree: 1.4%
- Strongly Disagree/Disagree: 0.7%
If the circle on the Blue Label appears White, the temperature limit has NOT been reached.

If the circle on the Blue Label appears Red, the temperature limit has been reached.

**Figure 9.** The Incidence of Indicators Alerting Patients That Their Medicine Had the Potential for Heat Damage Occurred in Less Than 2% of Shipments

Does the circle on the blue label of the TransTracker®F appear red?

1.5%

98.5%

**Figure 10.**
About the Authors:

**Bill Bailey, RPh** is a pharmacy industry expert with more than 30 years of leadership experience, holding key positions at leading organizations engaged in specialty, retail, mail service, and health systems pharmacy, and PBMs. He is currently COO of Citizens Rx, a full-service national PBM offering claims processing, formulary management and prescription network management services.

**Daniel Kus, RPh** is an industry veteran with extensive experience in operational management, quality performance initiative implementation and enhancing standards of practice within HMO/managed care organizations. He is Vice President of Pharmacy Advantage Specialty Pharmacy, a Michigan-based organization providing compassionate care and comprehensive medication therapy management programs to patients with acute and chronic conditions.

References


