



Don't Let Your  
Future Be  
Frozen  
Out



**ColdChainIQ**  
Temperature Control Logistics  
& Quality Network







# Don't let your Future be Frozen Out

Two prime profiles of what not to do in cold chain logistics recently were presented within two US criminal investigations.

May this year witnessed the **\$33m case** featuring US firms SB Medical Inc. and TC Medical Group – both based in Toronto, Canada and St. Michael Barbados, plead guilty to their involvement in a multi-year medical conspiracy. (Indictment Case No. 1:14-cr-397).

In regards to the misdistribution practises regarding the pharmaceuticals in question, the FDA notice states: “Instead of storing pharmaceuticals at cool temperatures as required for many of the pharmaceuticals, members of the conspiracy used unregistered commercial mailboxes, residential backyards and porches, basement rooms, garages, kitchen fridges and freezers, which did not have adequate lighting, ventilation, temperature, humidity, and security as required for the safe storage and handling of the prescription drugs and devices.”

Also, back in 2013, a **guilty plea** was lodged by Gallant Pharma International Inc., headquartered in Arlington, Va., to two counts of importation fraud.

In the statements of facts filed with the plea agreements, Gallant Pharma admitted that the company sold “cold chain” drugs and shipped and received those drugs with ice packs that sometimes melted, and were not with dry ice used by legitimate drug distributors.

Of course cases of this extremity are rare, however most cold chain suppliers will have faced the occurrence of spoiled pharmaceuticals when quality control has slipped.



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## The Cost of Quality

Undoubtedly, the supply chain is complex to navigate with the maintenance of quality and security being of prime focus. New compliance requirements have translated into additional expenses for cold chain suppliers to account into their overheads, leaving many of these commercial firms searching for the most cost-efficient solutions.

Although, amidst the corporate pressure to heighten cost –efficiencies and financial savings in the cold chain, the industry must not let its focus on the gravity of compliance responsibilities waiver.

Cold Chain IQ has compiled a set of key considerations to contemplate should you be presented with the temptation to cut corners in quality in the name of costs.

### **Don't Just Take The Vendor's Word For It**

According to the Centers for Disease Control and Prevention's (CDC) estimation, around \$300 million worth of vaccines alone are lost annually due to improper storage and distribution.

Emilie DeGlise of Celgene International mentions that when it comes to data on effectiveness of transport packaging: "Don't be too confident in what the suppliers give you because it [does] not always represent the reality of a shipment."

**“ I have heard stories of alleged cold rooms being available in certain airports, but once you go on-site you find there is not even a thermometer installed.**

**- Eugenio Fillippi**

“To give you an example, some ... test their blankets in a thermal chamber but it's not representative at all because in a thermal chamber you have temperatures but you don't have the sun shining, you don't have the humidity, so the real conditions are not [there].

“The real condition is that your shipment is changing temperature all the time, it could wait on the tarmac [for] two, three, four hours, could then be in a plane - a very cold temperature and etc...”

### **Choose Your Partners Wisely**

On the matter of selecting which third party providers to work with, Eugenio Filippi, Pharmaceutical Logistics Senior Manager, notes that it pays to ensure they are trustworthy.

“I have heard stories of alleged cold rooms



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being available in certain airports, but once you go on-site you find there is not even a thermometer installed.

"If it is a new partner, a new lane, a new process, who should you trust with the data gathering?"

"If someone in a sub-tropical region of the world, for example, swears to you there are enough electrical outlets to recharge your box, do you take it at face value, ask for evidence, fly in to check it in person?"

"Would you entrust the truck driver of your shipper, for instance, to perform the on-site inspection to determine the high and low risk elements of the route in question? Does the person have the understanding or know-how to perform such a task?..."

"Once you have all the relevant data I do agree that doing a proper qualification should be rather straightforward, however, I have yet to see a simple "how to" guide to tackling the nitty-gritty of gathering such information in different countries, involving potentially dozens if not hundreds of partners.

"Ultimately, who do you trust?"

## Don't Neglect The Drivers Of The Supply Chain

The Freight Transport Association notes



that the logistics industry is suffering a driver shortage.

With the driver industry suffocating from an aging workforce and a lack of new entrants – down to licence acquisition, lack of

understanding, poor sector image and low quality driver facilities.

Some predict that a plummeting supply of drivers could spark a rise in price point in the near future.

## Don't Charge Ahead Without A Crisis Plan

In an unforeseen crisis, a contingency plan can facilitate extensive damage control.

On this matter, World Courier notes:

"It is important that all personnel take contingency planning seriously—even if the events which would trigger the plan seem remote and unlikely."

"Contingency planning is the process that prepares us individually, corporately and on a local and global level to respond coherently

to an unplanned event.

Being involved in logistics and supply chain, it's easy to focus on big international events with intercontinental travel or problems with the weather. But it's equally important to consider smaller and more local issues."







“What happens if norovirus spreads through the entire office staff? What happens if a supplier goes out of business?”

## Don't Leave Your Data To Gather Dust

Data has ground-breaking potential for the healthcare industry. In a recent study by Capgemini, organizations reported an average 26% improvement in performance due to their use of big data analytics, with respondents expecting to see a full 41% improvement over the next three years.

In regards to utilising data analysis within cold chain, Emilie DeGlise of Celgene International notes that within the results some surprises may surface. “For example, we felt that shipments take only two days but at the end you see that, no, it's taken five days. But you can analyze very professionally where you [have] “lost” time and then you can begin to improve with your carriers or with your partners...”

## Don't Allow Fraud To Burrow Its Way into Your Cold Chain

Remember a long supply chain only needs a single weakness for a breach to take effect. So investment in quality security systems is vital. Pfizer notes that recent years have seen a significant rise in the level of counterfeit medicines reaching consumers across Europe through illicit sources such as the internet as patients scout the web to find cheaper offers with an element of convenience.

The EU's Falsified Medicines Directive looks to safeguard the integrity of pharmaceutical supply chain from the presence of falsified medicines. Implemented in 2011, this directive influenced the cold chain with added control obligations in regards to starting materials and inspections of active substance producers and excipients in medicines.

View Cold Chain IQ's Cold Chain Compliance Milestones [here](#).

## Regulation Penalties Are Costly

The consequences of mishandling pharmaceuticals not only translate into substantial health risks for consumers and detriment to consumer trust should the news hit the public domain in a big way, but also in the form of penalties. E.G License suspension, refusal, restrictions from importing and sale in Europe. In response to those tempted to risk compliance levels slightly to keep costs down, Nigel Wing of Global Head Life Sciences & Healthcare, DHL Global Forwarding notes: “Amongst other aspects, we are talking about patient safety, product efficacy, high values & company brand reputation. For a responsible company this type of risk is not acceptable or sustainable long term.”



To conclude, although your bottom line may endure slightly more stress due to added GDP requirements, it certainly pays to ensure your priorities do not become distracted by the presence of attractive costs.



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