

Comments

Comments to Maine Department of Environmental Protection

December 7, 2022

Room 101

Deering Building

90 Blossom Street

Augusta, ME 04330

Hello, my name is Thomas J. Pizzuto.

I am founder of DecomRx Corporation; an early-stage company located in Malvern, PA.

I appreciate the opportunity to appear before you today to provide comments about exempting certain federally regulated products, in this case, pharmaceutical product packaging, namely HDPE bottle & closure systems and folding cartons.

While my comments are specific to pharmaceutical sellable unit packaging, they may also apply to other product packaging materials, where recordation of its final disposition holds value beyond compliance.

To give context to my comments, my educational background includes among other degrees, a Master of Science degree, Quality Assurance & Regulatory Affairs from Temple University School of Pharmacy.

Professionally, I have worked in the pharmaceutical industry for more than 20 years with positions at Wyeth Pharmaceuticals and Johnson & Johnson Supply Chain.

At Wyeth, I was responsible for corporate purchases of plastic (HDPE) bottle and closure systems.

The role of pharmaceutical unit packaging is to provide chemical protection and containment, portion control and security to maintain drug quality.

Here in the United States, the predominant package system used to distribute drugs is High-Density Polyethylene, or (HDPE).

It is estimated that more than 4 billion HDPE bottles & closures enter and exit U.S. drug supply chain annually.

Like its name suggests, HDPE is a high-density plastic with a semi- to non-porous surface that is very stiff, has a good temperature resistance and water vapor barrier.

These physical properties are why FDA approved HDPE as a packaging material for food and drug.

Since it is non-biodegradable and can take centuries to breakdown, it is imperative these containers are recycled.

As a point of note, EPA recently developed guidelines regarding empty pharmaceutical containers and determined that any residue is nominal and not considered hazardous.

Recycling HDPE has benefits.

Studies have shown that it is more cost-efficient to produce a product from recycled HDPE than it is to manufacture 'virgin' HDPE plastic, where 1kg of HDPE requires 1.75kg of oil to manufacture.

Moreover, ESE World B.V. carried out tests to demonstrate that HDPE can be recycled at least 10 times.

At Johnson & Johnson (Supply Chain), I was the program director, responsible for the design-development and deployment of product serialization and traceability systems and processes to comply with regulations across 46 different countries.

Here in the United States, the Drug Supply Chain Security Act, signed into law in Nov. 2013, requires segments of the supply chain to achieve product serialization and traceability capabilities over a ten-year period, ending November 27, 2023.

At J&J, I oversaw development and execution of a global program responsible for the retrofit of packaging lines, label artwork changes, and new IT systems to uniquely identify every sellable unit, and track & trace those units from packaging to internal distribution to external, authorized distributors of record.

I authored capital appropriation requests.

With every request submitted came the management review and challenge to show what value product serialization and traceability investments could provide beyond compliance to the law.

"Value Beyond Compliance" (VBC) became a tag line for those use cases that leveraged serialization and traceability for purposes other than compliance.

My team and I explored use cases – locally and globally, with and without consultants, to develop a list of use cases organized along our internal and external supply chain.

Many of these use cases were internally focused, where enabling them required coordination across internal plants and distribution centers, while others had an external focus and included coordination with J&J trading partners.

I mention this because the data collected during a recently conducted pilot using empty, plastic pharmaceutical bottles enables several VBC use cases.

In September 2019, I left J&J and founded DecomRx for the purpose of 'decommissioning' empty, serialized, pharmaceutical sellable units.

Decommissioning had been an interest of mine since 2007 when working with RFID and I learned that commands can be issued to an RFID tag to self-destruct or decommission itself.

Over the course of 3 years and one pandemic, I designed and developed, installed, and tested, a semi-automated, drop-to-light system to process empty, serialized, pharmaceutical sellable units. I mounted the system along with a battery pack, inverter, electric motor and two shredders inside a van.

I then conducted a 90-day pilot with several forward-thinking pharmacies in Southeastern, PA to determine if processing and recycling of end-of-life stock bottles could be cost-effective and self-sustaining.

Instead of discarding empty stock bottles, participating pharmacies held them aside for pickup and processing either curbside or alternate location.

The empty containers were imaged, and the serialized product information (SPI) printed on its label was decoded and adjudicated.

Adjudicated units were either retained or shredded. Retained units were held for subsequent analysis. Shredded units included HDPE bottles and folding cartons.

Information decoded from the 2D data matrix barcode include GTIN, Serial Number, Lot, and Expiration date, or serialized product information. This information was enhanced to include high-definition image, time and date stamp and zip code comprise 'event' data.



Event data, taken individually and in the aggregate, were analyzed for application across a range of use cases discussed below.

Over the next 90-days, a total of 70 pickups were made with an average of 88 bottles per pickup for a total of 6,125 bottles processed, representing 240 lbs. of shredded HDPE, which, at the time, had an average price for shred of \$0.64 / lbs. on the secondary materials market for a total of \$160. Since pick-up and processing of the bottles was free-of-charge to the pharmacies, an estimated \$120/week, cost avoidance was accrued over the course of the pilot.

HDPE bottles processed ranged from 23cc @ 0.3 oz to 2100cc @ 4.6 oz.

For reporting purposes, after weighing 1,500 bottles, we derived an average weight of 0.623 oz. per bottle.

HDPE closures ranged from 0.1oz to 0.3oz, with an average of 0.186 oz per closure.

Also, a paper pamphlet known as an 'outcert' accompanies each bottle-closure system. These outcerts detail FDA required instructions for use.

Based on our data, these outcerts weigh 0.1 oz – 0.3 oz with an average of 0.2 oz per outcert. Extended this average weight across total bottles processed yielded 76.5lbs of paper. In summary, the average HDPE bottle closure system + outcert weighs:

HDPE bottle	=0.62 oz
Closure	=0.18 oz
<u>Outcert</u>	<u>=0.20 oz</u>
Total	=1.00 oz

Extrapolating these results across an estimated 164 community pharmacies yields the following directional estimates. Additional data collection and analysis is required to confirm them.

Estimates exclude optical-related businesses since they typically do not dispense drugs but refer patients to traditional pharmacies.

Large chain drug stores were also excluded since the pilot focused on smaller, community pharmacies. It is, however, reasonable to assume larger chain drug stores dispense at least an equal, if not greater amount of drug products, so the estimates below would be expected to increase.

Pharmacy locations (source: Hoovers):	164	Excludes optical & chain drug stores
Bottles emptied/pharmacy (daily rate):	17	Derived from PA pilot results
Bottles emptied/pharmacy (yearly rate):	5,304	Daily rate x 312 business days(M-S)
Bottles emptied/pharmacy (yearly rate):	869,856	Daily rate x 164 pharmacy locations
HDPE bottle-closure weight (yearly total):	43,492 lbs.	HDPE waste (0.8oz / bottle-closure)
Paper outcerts weight (total yearly rate):	10,873 lbs.	Paper waste (0.2oz / bottle)

At the close of the pilot, I took the data I collected and developed 5 dashboards.

These dashboards represent the primary objective of my pilot. Namely, to demonstrate the value beyond compliance of data gleaned from these discarded serialized sellable units.

This objective underpins my comments today, in that, recycling can transcend the physical materials collected.

It can also include data gleaned from the containers being recycled, where the effect is to enhance the value of these recycled containers because the data is many times more valuable than the HDPE alone.

By linking the physical and digital, it provides producers with an incentive to recycle because the data helps them better manage their inventory, improve their forecasts, etc. The savings / cost avoidance could, in turn, help offset costs where other recycled materials are not as valuable either physically, digitally, or both.

The intent of my comments is to dissuade Maine regulators from exempting federally regulated pharmaceutical sellable unit product packaging such as HDPE bottles and folding cartons. On the contrary, this waste packaging is exactly the kind of material Maine and every other state contemplating EPR legislation should look for to promote physical and digital circularity.

Thank you for the opportunity to provide my comments.

Respectfully submitted,

Thomas J. Pizzuto
Founder
DecomRx Corporation

DISCLOSURE:

Thomas is the holder of two (2) U.S. patents applicable to decommissioning

- US 10,062,049, Systems and Processes for Tracking Items
- US 8,542,09, Systems and Processes for Tracking Items