Wood Pallet Industry

Refutes

Tylenol Recall Assertions

In 2008, Tylenol users complained to McNeil Consumer Healthcare, a subsidiary of Johnson & Johnson and manufacturer of Tylenol, of a "musty odor" coming from pill bottles.

A subsequent Food and Drug Administration (FDA) report charged there was "an increasing trend of uncharacteristic smell consumer complaints for Tylenol Arthritis Caplets" throughout 2009. That FDA report says "no formal investigation was conducted" despite a number of complaints associated with gastrointestinal problems.

The FDA report is dated January 2010. On what basis, then, did McNeil say last November that wood pallets were the root cause? The company has not provided documented evidence for a source of the contamination of its pharmaceuticals.

McNeil speculates that a chemical called 2,4,6 tribromophenol (TBP), was used to treat lumber that was used for wood pallets and that chemical broke down into 2, 4, 6-tribromoanisole (TBA), the chemical tainting the medication.

There are more than 1.2 billion pallets in circulation everyday in the United States alone. They have been used safely for over a half century by diverse industries including produce and pharmaceuticals.

Complaints & Recalls Timeline

Sept. 2008	Approximately 76 consumer complaints about uncharacteristic musty odor in Tylenol Arthritis Relief Caplets; eight complaints were associated with gastrointestinal distress. McNeil conducted organoleptic examination, macroscopic and microscopic examinations but "failed to conduct testing to evaluate the possibility of chemical contamination or other change or deterioration in the distributed drug product."*
April 2009	Approximately 39 musty-moldy odor consumer complaints; three adverse event reports. McNeil told FDA contamination was from wood pallets, but "did not extend the assessment of the event to other products that received packaging components from the same suppliers."
Nov. 2009	McNeil announces a limited, voluntary recall of five lots of Tylenol Arthritis Red EZ-Open Cap due to consumer reports of a moldy odor that can reportedly cause nausea and stomach pain.
Dec. 2009	McNeil expands voluntary recall to all lot numbers of its Tylenol Arthritis Pain caplet 100 count bottles with the red EZ-open cap.
Jan. 2010	McNeil in consultation with the FDA expands recall to non-Tylenol products including Motrin, Benadryl Allergy Ultratab, Rolaids Antacid Tablets, Simply Sleep and St. Joseph products.

* Quotations in this section are from the FDA's Jan. 8 field investigation report.

Since the McNeil-company recalls, NWPCA members have reported that McNeil/Johnson & Johnson and other pharmaceutical companies have announced new wood pallet requirements that do not resolve their problems. For example, the company issued a requirement that suppliers must provide new pallets that have been heat-treated exclusively and stamped with the ISPM 15 HT mark.

ISPM 15 is an international treatment and marking system designed to address the movement of non-native invasive species of wood-related pests. It has nothing to do with chemical taints.

As for limiting pallets solely to newly manufactured ones, if the source of the chemical odor is a shipping container floor, as in the Australian beer case (or any other supply chain location), that smell will spread to the pallets whether they are new or recycled wood pallets, or plastic pallets.

If a chemical can spread from a shipping container, pallet, corrugated box or material handling equipment through a plastic bottle with a foil-sealed lid and taint the medicine, then McNeil has a problem that has nothing to do with wood pallets and everything to do with their primary packaging and quality control standards and practices.

The NWPCA suggests McNeil, instead of implementing arbitrary pallet specifications, form a supply chain task group that can address the issue from the various points of product contact. The knowledge exchange from such a group would likely have benefits across the supply chain and greatly increase consumer confidence in the handling of vulnerable goods.

(more)

About this NWPCA End User Handout

We have included a timeline on the McNeil drug recall and a brief overview of the FDA investigation. We are providing as a separate document, the facts about the chemicals involved; that piece demonstrates the pervasiveness of the chemical throughout the supply chain. You may want to provide this entire package to your customers, or you may prefer to limit your distribution to the chemical fact sheet. We have designed this handout to give you flexible options depending upon your communication needs with your individual customers. This fact sheet is available on the NWPCA website at www.palletcentral.com in a printer-friendly format. It is currently featured on the home page; if you need to access it in the coming months you will be able to find it in the Industry Marketing/Marketing section posted under Customer Handouts.

McNeil Assertions vs. FDA Investigative Report

McNeil's publicly stated theory of the wood pallet as root cause has not been validated by either McNeil/Johnson & Johnson or the U.S. Food and Drug Administration (FDA). In fact, on January 15, 2010, the FDA issued a warning to McNeil President, Peter Luther, which among other concerns stated:

> *You (McNeil) have concluded that TBP from the wooden pallets degraded into TBA, which contaminated product containers and the finished product in those containers.*
>
> *We (FDA) have concluded that your company did not conduct a timely, comprehensive investigation.*
>
> *Your initial investigation into the root cause of the odor was unjustifiably delayed and terminated prematurely. Numerous complaints were received over a four month period in 2008 before they were considered a trend and before actions were initiated to determine the root cause. When microbiological testing in August 2008 did not support an initial speculation that microbial contamination was the root cause of the odor, the investigation was closed. No other possible root causes were pursued. Your firm lacked adequate justification for this decision.*
>
> *...you concluded that the most probable root cause of the odor in the Tylenol Arthritis Relief caplets was the exposure of drug product bottles to wood pallets chemically treated with TBP. You did not expand the scope of the investigation to other lots and products potentially affected by this deviation. This would include, for example, products packaged in bottles from the same supplier that used the same type of wooden pallets, and other products manufactured by your facility for which odor complaints were received.*
>
> *...your firm's analysts noted that the tablets, once removed from the bottle, did not have an unusual odor but the bottle retained a strong odor. Nonetheless, you did not pursue chemical testing at that time.*
>
> *Neither this letter nor the observations noted on the FDA-483 is intended to be an all-inclusive list of the deficiencies that may exist at your facility.*

In correspondence to executives at McNeil and Johnson & Johnson, NWPCA demanded "definitive evidence that the source of the contamination was TBA" as well as "technical and scientific theory as to how this chemical could spread from a tertiary packaging component to a primary packaging component through various layers of cardboard and plastic packaging surrounding the primary product."

In a response letter dated February 2, 2010, McNeil said the company had conducted testing but that the results are proprietary information that it will not share with NWPCA. If the company genuinely wants to fix its problem, why would it hide important data from the very industry it has accused – the very industry upon which it continues to rely for providing safe transport platforms?

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Facts About the Chemicals in the Tylenol Recall

NWPCA has continued to follow up on this issue, talking with a number of authorities including chemists, chemical engineers, clinical laboratory technicians and academics in the chemistry field. The following are technical facts gathered from a review of literature and discussions with experts.

Taints

Taint arises normally from external sources and is responsible for unpleasant odor or taste in fresh, processed and packaged food. Organohalogen taints that are known to affect the food and beverage industries are the halophenols and haloanisoles. Halophenols are derived from chlorophenols (i.e. mono-chloro to pentachlorophenol). The haloanisoles found most often in food products are:

- pentachloroanisole (PCA)
- 2,4,6 trichloroanisole (TCA)
- 2,3,4,6 tetrachloroanisole (TeCA) and
- 2,4,6 tribromoanisole (TBA)

Haloanisoles are very powerful odor compounds with odor thresholds in the low part-per-trillion (ppt). Haloanisole contamination can be traced to raw materials (e.g. plastic resins), packaging (e.g. bottle, can, paperboard products), shipping containers and wood packaging.

Analysis of tainted material can determine if haloanisoles are the source of the unusual odor and may suggest possible origins of contamination. Typical analysis utilizes an automated extraction of the haloanisole, followed by gas chromatography (GC), and then detection by mass spectrometry. New technology such as ultrahigh-speed short column GC enables real-time analysis.

2,4,6 tribromophenol (TBP)

TBP can be derived from a variety of natural sources such as marine algae and marine animals. TBP is readily formed from chlorination of water containing phenol and bromide. TBP is used as: a) a wood preservative; b) general fungicides for the leather, textiles, paints, plastic, paper and pulp industries, c) a flame retardant agents in epoxy resins, polyurethanes, plastics, paper, textiles and fire extinguishing media; and d) an antiseptic agent. TBP has also been found in detergents containing bromine.

TBP is not used as a fungicide treatment for lumber or wood pallets in the United States. Imported material that has been treated with TBP for use as a fungicide is barred from entering the United States.

Chemtura and ICL (TBP companies in the United States and Israel, respectively) have clarified that although TBP is not registered with the Environmental Protection Agency (EPA) as a wood preservative, they both manufacture, sell and distribute TBP for other uses.

2,4,6 tribromoanisole (TBA)

TBA is produced by the conversion of its precursor TBP by microbial activity under humid and warm conditions. This conversion is caused by the following fungi:

- *Cladosporium* spp. - widely distributed in air and rotten organic materials.
- *Fusarium* spp. - widely distributed on plants (e.g. rice, bean, soybean) and in the soil.
- *Paecilomyces variotii* - inhabits soil decaying plants and food products.
- *Penicillium* spp. - widespread and can be found in soil, decaying vegetation, and in the air.
- *Trichoderma longibrachiatum* - widely distributed in the soil, plant material, decaying vegetation and wood.

Once TBA becomes airborne, it can attach itself to any surface and can cause contamination. Sensory threshold of TBA ranges from 0.008 – 0.03 ppt for water, and 2-6 ppt for wine. Even very low levels of TBP and TBA in water, fish and crustaceans could pose serious contamination problems.

In simple terms: TBP + mold + moisture = TBA.

Since TBP is used for such a wide variety of diverse applications (but not as a wood preservative due to EPA restriction) and the molds that need to interact with TBP can be found practically anywhere, the likelihood that TBA came from sources other than wood pallets is a distinct possibility. Other packaging materials and even shipping containers have been sources of contamination in the past. Also, TBA is not the only taint that could have caused the McNeil recall. TCA widely known as "cork taint" also causes problems in food packaging and in water distribution.

In one case involving beer in Australia, TBA was identified as the taint. TBA and TBP were detected in the beer, empty cans, paper, fibreboard dividers and flooring of the shipping container. Only TBP (not TBA) was detected in the wood pallet and it was linked to environmental contamination since TBP was confirmed not used for treatment. It was proposed that the high TBA and TBP concentrations on the shipping container flooring was the source of contamination, the flooring contaminated the packaging materials and can liners, and then the TBA leached from the can liner to the beer. The table below shows the degree of TBA and/TBP contamination.

	Beer	Pallet Lumber	Paper	Divider	Container Flooring
TBA (ng/kg)	10-40 ng/L	–	20-370	3000	15 million
TBP (ng/kg)		260-17300	9100	8900	43 million

* Source: "Environmental Taints – An Industry Review of Tainting Due to Halogen Phenal Derivatives" Peter David & Bill Taylor – Lion National Limited, Australia.