

Tylenol Tragedy

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Dear Editor, Pharmawave

Tylenol is the brand-name of paracetamol formulation manufactured by Johnson & Johnson (J&J) which is majorly sold in USA. Tylenol (capsule form) & J&J, both were doing good – health and business wise. As a molecule, Paracetamol is a trusted entity having proven safety and efficacy features over several decades. Apart from that, in specific - J&J's gelatin-based Tylenol capsule used to have acceptance and appeal as those were looking slick and easy to swallow.

It was an incidence of 40 years back! In September & October of 1982, a series of death happened at USA for “unknown”-reason. Investigation revealed that all the persons who died took Tylenol within 24 hours of death. The signal was clear and all believed that there must be a common thread between all the deaths. Within a short time, chemical analysis of those Tylenol capsules (filled in the same bottles consumed by persons who died) uncovered the mystery. Tylenol was contaminated with potassium cyanide!

Without any delay, J&J initiated an emergency market recall of Tylenol from the market. They arranged a massive campaign to collect Tylenol from Pharmacy to Pharmacy, advertised in newspapers, and used loudspeakers to reach the people of USA (especially Chicago). In this process, around 31 million bottles of Tylenol recovered which were in circulation. In fact, J&J also offered the replacement of capsules to those who purchased the capsules.

As a routine practice, J&J & health authorities facilitated analysis of control samples (capsules of same batch numbers archived at the company) and nothing wrong was found. Authorities announced rewards for anyone who could give any clue to find the culprit who masterminded the plan to contaminate Tylenol. Yes, certainly it was a case of mass and random murders. This is one of the worst pharmaceutical conspiracies could happen in the history.

Several investigation teams were formed to uncover the truth. J&J and Government Health Agencies spend lot of resources. Despite massive efforts from all relevant corner mainly by Police and other investigation agencies, the root cause of the Tylenol disaster could not be revealed yet. In fact, after 1982 fresh attempt was made around 2009 to find the reason – still it remained inconclusive.

When, investigation was at pick around 1982, one man, namely James Lewis, sent a letter to J&J claiming himself as killer of Tylenol disaster and demanded \$1 million in exchange for

stopping the poisonings. However, at later time, police and federal investigators understood that James Lewis had no connection to the Tylenol case. James wanted to use the situation wanted to make money. He was sentenced to jail for 13 years for this fraud.

However, this Tylenol tragedy paved way to a road map on how to prevent such product tampering. J&J innovated and implemented multiple methodologies and gates to protect the final product especially by implementing tamper-proof packaging. Consumers must not use the medicines if those packaging features are compromised.

J&J, over the course of time, researched and introduced a new form of capsules — named “caplet” —coated with the same gelatin but much more difficult to tamper with compared to earlier capsules which could be easily opened and contaminated.

The effort of J&J is praised worldwide for its action and efforts to tackle Tylenol massacre.

Nowadays we can see multiple such examples to judge the authenticity of the manufacturer of medicines. A few of those are the QR code, tamper-proof stickers, tamper-proof bottles, invisible signs (what the manufacturer knows), and many more. These are called anti-counterfeit features however are popular in currency notes (an impression of Gandhiji what we saw within the white part of notes in India)(1, 2).

References

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