Alvogen – Recall of fentanyl transdermal system

- On January 31, 2025, Alvogen announced a voluntary, consumer level recall of one lot of fentanyl transdermal system 25 mcg/h because there is a potential that patches could be multi-stacked, adhered one on top of the other, in a single product pouch.

- Fentanyl transdermal system was distributed nationwide.

Product Description	NDC#	Lot# (Expiration Date)
Fentanyl Transdermal System, 25 mcg/h; Five individually wrapped and labeled pouches	47781-424-47	108319 (4/2027)

- Fentanyl transdermal system is indicated for the management of severe and persistent pain in opioid-tolerant patients, that requires an extended treatment period with a daily opioid analgesic in opioid-tolerant patients, and for which alternative treatment options are inadequate.

- There is a possibility that the application of a multi-stacked 25 mcg/h patch could result in serious, life threatening, or fatal respiratory depression. Groups at potential increased risk could include first-time recipients of such patches, children, and the elderly.

- To date, Alvogen has received one serious adverse event related to this recall.

- Anyone with the affected lots on hand should stop distribution and return product.

- Patients that have fentanyl transdermal system subject to this recall should immediately remove any patch currently in use and contact their health care provider. Patients that have fentanyl transdermal system should contact their healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

- Contact Alvogen Customer Complaints by phone at **1-866-770-3024** or by e-mail at **alvogensmb@continuumindia.com** for questions regarding this recall.