

42 U.S. Code § 247d-6d(c)

DEFINITION OF WILLFUL MISCONDUCT

An act or omission that is taken—

- (i) intentionally to achieve a wrongful purpose;
- (ii) knowingly without legal or factual justification; and
- (iii) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.

42 U.S. Code § 247d-6d(c) (5)

EXCLUSION FOR REGULATED ACTIVITY OF MANUFACTURER OR DIST.

(A) In general

If an act or omission by a **manufacturer** or **distributor** with respect to a **covered countermeasure**, which act or omission is alleged under subsection (e)(3)(A) to constitute willful misconduct, is subject to regulation by this chapter or by the **Federal Food, Drug, and Cosmetic Act** [21 U.S.C. 301 et seq.], such act or omission shall not constitute “willful misconduct” for purposes of subsection (d) if—

(i) neither the **Secretary** nor the Attorney General has initiated an **enforcement action** with respect to such act or omission;



42 USC § 247d-6d(i)(10) Serious Physical Injury

The term “serious physical injury” means an injury that— (A) is life threatening; (B) results in permanent impairment of a body function or permanent damage to a body structure; or (C) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

42 U.S. Code § 247d–6e(d)(1) EXHAUSTION

Subject to paragraph (5), a **covered individual** may not bring a civil action [for willful misconduct] against a covered person **unless such individual has exhausted such remedies as are available under [CICP] if the Secretary fails to make a final determination on a request for benefits or compensation filed in accordance with the requirements of this section within 240 days after such request was filed, the individual may seek any remedy that may be available under section 247d–6d(d) of this title.**