



BACKGROUND

Contact: **Rend Al-Mondhiry**
ral-mondhiry@crnusa.org / (202) 204-7672

CRN Debunks Widely Cited AER Statistic for Supplements

The often-cited statistic that the Food and Drug Administration (FDA) receives “less than one percent of all adverse events associated with dietary supplements” is based on outdated, irrelevant data. The statistic is being misinterpreted and used to support the need for overreaching regulations or potential new laws that would impose pharmaceutical-like regulation on supplements. What’s missing from this assumption is that the numbers may be low because supplements are among the safest FDA-regulated products, especially when compared to drugs, and not because manufacturers are failing to report serious adverse events. Here are some additional problems with this statistic.

The data is outdated and irrelevant.

- The “less than one percent” statistic originated from an FDA-commissioned study¹ released in 2000. It pre-dates the 2006 law that requires dietary supplement manufacturers to report serious adverse events to FDA² and is therefore outdated.
- Even more troubling, it’s not about dietary supplements. The author of that study bases this “less than one percent” finding on *prescription drug and vaccine related adverse event data* – NOT dietary supplement related data. It is a “best estimate,” following a conclusion that the reporting rate of drug and vaccine adverse events “is very low” and that supplements are likely to be similarly under-reported.³
- The original study reads:

“Yet it is clear ...that the rate of reporting of drug and vaccine adverse events, even in countries where there are well-advertised and effective systems for identifying events, is very low. It is probably not more than one percent, except when the event is readily recognized, severe, and clearly related to the exposure in the mind of the treating physician.”⁴

Then based on comparisons to drug and vaccine reporting at that time, the author concludes that, “[a] best estimate is that less than one percent of serious adverse events caused by dietary supplements is reported to the FDA.”⁵

¹ A. Walker, *The Relation between Voluntary Notification and Material Risk in Dietary Supplement Safety*, FDA Commissioned Paper, March 9, 2000.

² The Nonprescription Drug and Dietary Supplement Consumer Protection Act, Pub. L. No. 109-426, 120 Stat. 3469 (2006).

³ Walker, *supra* note 1, at 10-11.

⁴ *Id.* at 10.

⁵ *Id.* at 11.

The data is being misinterpreted.

- Despite this flawed assumption, the “one percent” statistic has taken on a life of its own, appearing in the media; cited in conferences and scientific journals; referenced by the HHS Inspector General⁶ and the GAO⁷; and reiterated by FDA itself.
- Critics of the supplement industry should take into consideration the fact that dietary supplements—the most popular products being vitamins, fish oil, and calcium—are simply less likely to result in adverse events than prescription drugs and biologics (i.e., vaccines).

The law mandates reporting of serious adverse events.

- In 2006, Congress passed a law requiring manufacturers to report all serious adverse events they receive to FDA. The dietary supplement industry supported this law, which has been in effect since December 2007.
- FDA has the authority to take action against supplement companies that violate the law by failing to report. The agency has used that authority to issue warning letters, products recalls, and even bring an enforcement action against a firm that failed to file its adverse event reports.

The numbers show that dietary supplements are among the safest FDA-regulated products.

- Between 2007 and 2010, FDA received a total of 4,194 serious adverse events reports associated with dietary supplements over that four-year period.
- In 2010 alone, FDA received over 471,000 reports of serious adverse events related to drugs or biologic products—of this number, nearly 83,000 were deaths.⁸
- These numbers demonstrate the wide margins of safety that dietary supplements enjoy as billions of dosage units were sold during that same timeframe.

⁶ U.S. Dept. of Health and Human Services, Office of Inspector General, *Adverse Event Reporting for Dietary Supplements: An Inadequate Safety Valve*, OEI-01-00-00180 (2001).

⁷ U.S. Government Accountability Office, Testimony Before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives, *Dietary Supplements Containing Ephedra: Health Risks and FDA’s Oversight*, GAO-03-1042T (2003); U.S. GAO, Report to the Chairman, Subcommittee on Wellness and Human Rights, Committee on Government Reform, House of Representatives, *Dietary Supplements: Review of Health-Related Call Records for Users of Metabolife 356*, GAO-03-494 (2003); U.S. GAO, *Dietary Supplements: FDA Should Take Further Actions to Improve Oversight and Consumer Understanding*, GAO-09-250 (2009).

⁸ AERS Patient Outcomes by Year (As of December 31, 2010), U.S Food and Drug Administration, available at: <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070461.htm> (last visited February 7, 2012).