European Journal of Molecular & Clinical Medicine

ISSN 2515-8260 Volume 02, Issue 04, 2014

Preemption, the Virus-Serum-Toxin Act, and the USDA: a case study using iatrogenic abortion due to BoHV-1 vaccines in pregnant cows

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Abstract

Three major vaccine manufacturers in the United States currently sell multivalent vaccines containing modified live bovine herpesvirus 1 (BoHV-1) for use in pregnant cattle. The first of these products entered the US market in 2003. Yet it has been known since the early 1960 s that vaccinal BoHV-1 causes abortion in cattle. The products became popular as they can be used year-round, regardless of pregnancy status in herds. Abortifacient effects have been considered to be minimal, provided initial vaccination is done during the previous 12 months using specific vaccine products and in accordance with label directions. Single nucleotide polymorphisms (SNPs) in BoHV-1 can be used to resolve whether post-vaccination outbreaks of abortion in cattle herds are iatrogenic (Fulton et al.; Vaccine. 2013; 31(11):1471-1479). We tested tissues from 10 abortion episodes (2010–2014) where an apparent association existed between recent use of modified live BoHV-1 and abortion 1–3 months later. Products were used on or off label in individual outbreaks. All 10 episodes had SNP patterns consistent with those of commonly-used modified live BoHV-1 strains (O' Toole et al.; Vet Pathol. 2014, In press). In spite of this, it is likely such products will remain on the market. This is due the absence of meaningful post-marketing surveillance of suspect adverse reactions in animals by the USDA, compounded by the courts' interpretation of the Virus-Serum-Toxin Act of 1913 [Lynnbrook Farms v. SmithKline Beecham Corp.,

Keywords:

and similar reactions in animals following use of federally licensed vaccines