ICAN
Informed Consent Action Network

VIA EMAIL & FEDEX

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Re: *Notice Regarding Error in Package Insert for GARDASIL-9*

Dear Dr. Gruber:

We write regarding an apparent error in the package insert for Gardasil-9. This insert indicates that the rate of systemic autoimmune disorders during the clinical trials for Gardasil was similar in (i) the saline placebo control group, (ii) the AAHS (aluminum adjuvant) control group, and (iii) the Gardasil group. Since the saline placebo group had no cases of systemic autoimmune disorders while the Gardasil group and AAHS control group had hundreds of such cases, a claim that they had similar systemic autoimmune disorder rates is inaccurate.

Gardasil-9's package insert (at page 8) states: "In total, 2.2% (351/15,703) of GARDASIL 9 recipients and 3.3% (240/7,378) of GARDASIL recipients reported new medical conditions potentially indicative of systemic autoimmune disorders, which were similar to rates reported following GARDASIL, AAHS control, or saline placebo in historical clinical trials."[1] (underline added.) This assertion is incorrect since the "saline placebo" group from the clinical trials for Gardasil had a zero percent rate of systemic autoimmune disorders. (See NCT00092547, "A Study of Gardasil (V501) in Preadolescents and Adolescents (V501-018)".)[2]

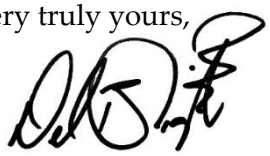
[1] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM426457.pdf
[2] https://www.clinicaltrials.gov/ct2/show/results/NCT00092547?term=nct+00092547&rank=1&sect=X430156 The "Serious Adverse Events" section for this clinical trial does not identify a single systemic autoimmune disorder and the FDA refers to this crlinial trial as the "saline placebo" group in its approval documents for Gardasil: https://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM094042

Since a zero percent rate of systemic autoimmune disorders in the "saline placebo" group is not similar to the over 2% rate in the "GARDASIL" or "AAHS control" group, the claim in the Gardasil-9 insert that these rates are similar is inaccurate.

Kindly advise if the FDA intends to correct the Gardasil-9 package insert to delete the words "or saline placebo" in the above quoted sentence from this insert. If the FDA does not intend to make this correction, kindly provide the support the FDA relies upon to assert that the Gardasil group, AAHS group and saline placebo group all had a similar rate of systemic autoimmune disorder.

Thank you for your timely attention to this request.

Very truly yours,



Del Bigtree

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