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To whom it may concern,

I am writing herein (5 pg. + reference list) in support of bill HB1161 (Christina's Law) which would require that consumers be given a supplemental information sheet regarding risk/benefit of the HPV vaccine prior to deciding about vaccination. By way of introduction, I am a PhD molecular biologist who has been researching and publishing articles on risks and benefits of HPV vaccines since 2012 in respectable peer-reviewed medical journals [1-10]. My research has focused particularly on the analysis of clinical trial data and the approval process of Gardasil HPV vaccine in order to examine whether the marketing claims by the vaccine manufacturer actually align with experimental evidence. To my dismay I found that there is no empirical support for the claim that HPV vaccines could reduce the incidence of cervical cancer beyond what has already been achieved through regular Pap screening practices whilst at the same time, HPV vaccine risks remain to be fully evaluated [2, 3, 5, 10]. Many reputable medical experts agree with this and their supporting published peer-reviewed articles are attached [11-16].

What is factual but rarely emphasized to consumers is that cervical cancer is an extremely rare and slowly developing outcome of a HPV infection in developing countries where regular Pap screening programs have been in place for many decades. In particular, the disease evolves over a period of several decades through a series of precursor lesions–cervical intraepithelial neoplasia (CIN), graded 1 to 3, leaving thus ample opportunity for timely detection by Pap-screening, and if necessary (in case of higher grade lesions CIN2 and 3) safe and efficient removal by either cryotherapy, laser therapy, loop electrosurgical procedure (LEEP) or cone biopsy [3, 11, 12, 15-17]. Therefore, although cervical cancer according to some estimates affects approximately half a million women world-wide on an annual basis [18], about 90% of new cases and cervical cancer deaths occur in low- and middle-income countries where regular Pap screening and treatment procedures are either non-existent or very limited [17]. In contrast, in developed countries cervical cancer mortality rates are extremely low (1.4-1.7/100,000 women) [2]. **The point of this is not to minimize the value of any human life, but simply to set the stage to answer a very critical question: could HPV vaccination further reduce the mortality from cervical cancer in the U.S., and improve on what has already been achieved through regular Pap screening procedures and routine medical care? The answer to this question from an evidence-based medicine (rather than marketing hype) perspective is a resolute and definite NO, because to this date there is no good data supporting the claim that HPV vaccination has led to a prevention of actual cervical cancer cases.** What HPV vaccines have been shown to actually prevent during clinical trials are mostly self-reversible HPV infections and lower grade CIN lesions associated with vaccine-covered HPV types [3, 11-13, 19]. Moreover, the key end-point for HPV

vaccine efficacy analysis was a composite surrogate end-point "CIN2 or worse" (which includes CIN2, CIN3 and adenocarcinoma in situ–AIS). However, due to the rarity of CIN3 lesions in HPV vaccine trials [11, 20], there is currently no good data on the impact of these vaccines on CIN3 [11], which is far more likely than CIN1 and 2 to progress to cervical cancer. Moreover, unlike CIN3, CIN2 is not an adequate prognostic marker for cervical cancer progression, and that not only due to relatively high regression rates, but also due to high misclassification rates, and poor reproducibility in diagnosis [11, 21-23]–a fact which was actually acknowledged even by the FDA Vaccines and Related Biological Products Advisory Committee (VRBPAC) members at their November 2001 meeting at which they discussed possible surrogate end-points for Gardasil-4 pre-licensure trials [12]. In addition, according to Philip Castle, who has recently been appointed director of the Division of Cancer Prevention at the National Cancer Institute [24], CIN2 is the least reproducible of all histopathologic diagnoses, and may in part reflect sampling error [22]. **Given therefore that CIN2 is not an adequate surrogate marker for cervical cancer, and moreover–that the vast majority of lesions in a composite CIN2/3 surrogate end-point are CIN2 lesions, Merck's choice and the FDA's approval of such a surrogate marker made it essentially impossible to evaluate Gardasil's clinical usefulness, as it cannot be assumed that any efficacy of the vaccine against CIN2/3 will actually translate to efficacy against CIN3–and ultimately–cervical cancer** [11, 12]. **Furthermore, in endorsing the CIN2/3 composite surrogate as a valid endpoint, the 2001 FDA VRBPAC failed to heed the warning from the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) E9 guidelines about surrogate variables which present two serious and relevant drawbacks in that regard: 1) that such variables may not be a true predictor of the outcome of interest; and consequently, 2) that they may not yield a quantitative measure of clinical benefit that can be weighed directly against adverse effects** [12, 25].

Now, how many parents are actually aware of these crucial facts when all the information they routinely receive from both vaccine manufacturer's advertising campaigns, as well as public health agencies, is that HPV vaccines are exceptionally safe and "life-saving" vaccines that will help in reducing the global burden of cervical cancer by up to 90%!! [10, 14, 26].

Next, it is necessary to briefly discuss Gardasil's safety record. A proper dealing with this topic would require a very lengthy article, however, as a brief summary, several points are to be noted: first, while the currently licensed HPV vaccines are regarded as having an excellent safety record, and without going too deep into the controversy whether this is actually true or no, it is generally recognized by the medical profession that no drug or vaccine is completely safe for all individuals. Secondly, it is likewise recognized that the true profile and rate of adverse reactions can never be adequately assessed during clinical trials given that: 1) these trials are usually of limited duration and are designed to primarily study efficacy and not safety; and, 2) they routinely exclude individuals with pre-existing medical conditions

and vulnerabilities, and thus do not adequately reflect the real-world population to whom the drug or vaccine product will ultimately be marketed [27, 28]. HPV vaccine trials were no exception in that regard. In fact, in their 2020 systematic review with meta-analyses of HPV vaccine trial data from clinical study reports Jorgensen et al. noted that,

"**As the included trials were primarily designed to assess benefits and were not adequately designed to assess harms, the extent to which the HPV vaccines' benefits outweigh their harms is unclear**" [29].

Given therefore that HPV vaccine clinical trial data fails to provide an accurate picture on safety, it is all the more necessary to carefully evaluate post-marketing vaccine safety data. In that context, note that since 2006 when the U.S. FDA licensed the first HPV vaccine for use in females from 9-26 years of age (Gardasil-4), and up to 24th of February 2023, the U.S. Vaccine Adverse Event Reporting System (VAERS) received a total of 47,651 adverse event (AE) reports related to administration of HPV vaccines, out of which 7,889 were serious (16.6%). What is however important to investigate is how do HPV vaccines in this regard compare to all other vaccines in the U.S. vaccination schedule (excluding COVID vaccines given that they were only recently introduced on the market, and were subject of much publicity which affects reporting rates). Table 1 below shows how: briefly, a simple disproportionality analysis, which is commonly used method in pharmacovigilance to identify potential safety signals [30], shows that in comparison to other vaccines routinely administered to 6-29 year old males and females (the main target group for HPV vaccination campaigns), HPV vaccines show statistically significantly greater number of AE reports that are serious, life-threatening and result in long-term disability. Notably, the odds of reporting a serious AE resulting in permanent disability is 3.5 times greater with HPV vaccines than all other vaccines excluding COVID vaccines.

Table 1. Reporting odds ratio (ROR) of serious AE categories for HPV vaccines in the U.S. VAERS from 2006 to February 24th 2023. The ROR is the odds of an AE of interest occurring with a particular vaccine product, compared to the odds of the same event occurring with all other vaccine products in the database. AE retrieved were from all locations for males and females between 6 and 29 years of age. Asterisk marks indicate statistically significant safety signals.

AE category	HPV vaccines (HPV2,4,9 & X)	All other vaccines excluding COVID vaccines	ROR	95% CI	p
Total	47651	105760			
All serious	7889	8934	2.15	2.082 - 2.221	<0.0001*
Serious NR	4385	3473	2.98	2.851 - 3.125	<0.0001*
Serious PD	2502	1638	3.52	3.307 - 3.753	<0.0001*
Serious life threatening	908	1398	1.45	1.333 - 1.578	<0.0001*
Death	202	430	1.04	0.882 - 1.233	0.655

Abbreviations: AE: adverse event; NR: not recovered; PD: permanent disability; HPV2: bivalent HPV vaccine Cervarix (GlaxoSmithKline); HPV4: quadrivalent HPV vaccine Gardasil (Merck); HPV9: nonavalent HPV vaccine Gardasil (Merck); HPVX (HPV vaccine non-specified brand); CI: confidence intervals.

What further needs to be highlighted is that while the vaccine manufacturers and many medical professionals frequently dismiss such AE reports as merely coincidental and not related to vaccination, and readily emphasize the inherent limitations of passive reporting drug safety surveillance systems, they forget to point out that these limitations work both ways–while it is indeed often difficult to conclude on the basis of AE reporting data that a vaccine caused an AE, it is equally difficult to conclude that it didn't [31]. With regard to HPV vaccination in particular, what is further notable is that the data from U.S. VAERS is highly consistent with that obtained from other AE reporting databases, including the World Health Organization (WHO)'s international database of suspected adverse drug reactions VigiBase [32]. **The various national and international vaccine safety surveillance databases not only show a disproportionally significantly higher reporting of AEs related to HPV vaccines in comparison to all other vaccines, but also, a remarkable consistency in the type of AEs that are disproportionally reported–with serious disabling systemic, neurological and autoimmune manifestations showing the highest safety signals** [32-34]**. Both of these factors–higher frequency, as well as consistency between AEs reported following HPV vaccination–strongly point to a causal and not merely coincidental relation.**

In addition, there are numerous reports published in peer-reviewed medical journals that strongly suggest that HPV vaccination is not safe for all individuals [2, 32, 34-69].

Note also that while HPV vaccines have thus far saved a grand total of ZERO lives from cervical cancer, they have positively prematurely terminated some. For example, very recently in 2021, Wellnitz et al. have reported a case of fatal acute hemorrhagic leukoencephalitis following Gardasil-9 vaccination in a 14-year old boy. His symptoms started 3 weeks following vaccination and worsened despite treatment with high dose steroids [70]. The authors of the report concluded the following:

"It is unclear why some individual patients develop ADEM or AHLE in response to an antigenic stimulus while most do not, but is likely due to differences in genes regulating the immune response. Indeed, ADEM has been associated with several specific major HLA histocompatibility class II alleles…While the epidemiologic data have failed to show a significant statistical association between HPV vaccination and ADEM or AHLE on a population basis, there have been multiple case reports published describing patients who have developed ADEM in the weeks following HPV vaccination. **These case reports strongly suggest that the HPV vaccination played a causal role in the onset of ADEM in the patients described. It is likely that the HPV vaccine can trigger demyelinating CNS disease in genetically susceptible individuals**. **Further research is needed to elucidate what those specific genetic factors are**." [emphasis added]

In the context of this paragraph, it is to be noted that what is presently claimed to be the primary evidence for the alleged “excellent” safety record of HPV vaccines are numerous epidemiological studies which seem to show that there is no statistically significant difference in the incidence of autoimmune and other chronic diseases among on one side–vaccinated individuals, and on the other–either unvaccinated individuals or the general population [71-75]. However, since the background rate of many autoimmune diseases is relatively low, and moreover, since the proportion of genetically susceptible people in the general population is very small, simple comparisons of the incidence of autoimmune diseases between those who have been vaccinated and those who haven’t are very likely to show no significant differences. Therefore, the safety of the vaccine cannot be asserted on the basis of such epidemiological studies since the inherent limitation of epidemiological/population-based pharmacovigilance approaches is that they fail to account for the *fact* that some adverse events are individually determined–i.e., determined on the basis of personal individual risk factors. This inherent limitation of epidemiology is well recognized among pharmacovigilance and medical experts [34, 38, 76].

Moreover, since it currently cannot be predicted to any satisfactory extent who will react adversely to HPV vaccination, given the fact that genetic and other personal risk factors are not sufficiently known, it is crucial that parents be informed that should they chose to consent to HPV vaccination, they could be exposing their child to an immediate serious albeit small health risk (that includes death) against still speculative vaccine benefits. **For vaccines with uncertain / unproven benefits designed to prevent a rare disease which develops many decades later in life and that is already very efficaciously preventable by Pap screening and routine and well-established medical interventions which carry no such risks, the risk to those vaccinated should be ZERO.**

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