Joint Committee on Health and Children  
Meeting on Thursday 3rd December 2015  

Opening Statement by Ms. Anna Cannon, REGRET

Chairman, Deputies, Senators thank you for hosting us today.

We are representatives of a group of parents who have come together from all over the country to form R.E.G.R.E.T, which stands for Reactions and Effects of Gardasil Resulting in Extreme Trauma. We are a support Group for families with children suffering long term and life changing health issues following the Gardasil HPV vaccination.

Our 130 daughters display a series of debilitating, long term and chronic symptoms, corresponding directly with the Gardasil Patient Information Leaflet (PIL)\(^1\) by the manufacturer. The PIL is the folded leaflet everyone gets included in the medication package when they go into the pharmacy to collect medication.

We are not given this information when signing the consent form for our daughters to get vaccinated with the Gardasil HPV vaccine in first year, secondary school. Instead we are given a marketing leaflet\(^2\), outlining five mild side effects. Nowhere does it tell us about the risk of long term, chronic life changing side effects.

It doesn’t tell us about the daily, severe headaches our girls struggle with for years, the nausea and stomach pains, the debilitating fatigue, the fainting and seizures, and onset of auto immune disorders.

It doesn’t tell us that we might regularly end up in the A&E department, watching our teenagers scream in pain, whilst doctors rule out one condition after the other.

It doesn’t tell us that our previously healthy, sporty and high achieving girls might never play sports again, never mind socializing with friends, enjoying what should be the most carefree time in their lives.

It doesn’t tell us about the impact of these illnesses on our daughters’ ability to continue their education, and the resulting psychological impact of having this basic human right taken away.

Parents are not prepared for the emotional strain of watching their child struggle to get out of bed to face another day of pain, fatigue, muscle weakness, dizziness and inability to concentrate. We also worry about how we will manage to raise the funds to meet our daughters many medical needs in years to come.

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\(^1\) See Supporting doc: Merck PIL.pdf  
http://www.merck.com/product/usa/pi_circulars/g/gardasil/gardasil_ppi.pdf

\(^2\) See Supporting doc: Parent Information Leaflet HPV Gardasil Vaccination.pdf  
http://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/hpv/HPVImmProg.html
Some of our daughters have contracted potentially life-threatening conditions, rare or unheard of in children their age. And yes, some doctors do admit that they think it is connected with the Gardasil HPV vaccination.

But most medical professionals in GP clinics, A&E departments and Hospitals across Ireland will not acknowledge any connection with this vaccine. Maybe if we as parents had been given the PIL, we could have pointed out the list of possible side effects to these doctors. Instead we struggled, sometimes for years, to understand our previously healthy daughters’ range of health issues, before making the connection.

We believe there is significant under-reporting of HPV vaccine adverse reactions to the HPRA (Health Products Regulatory Authority). Before contacting R.E.G.R.E.T., most parents had never heard of the HPRA, or the adverse reaction reporting system. It is also their experience that doctors and consultants failed to report suspicions of side effects even when parents had pointed out the connection.

We all wanted the very best for our children. We trusted that the HSE would act responsibly and respect our right as parents, to be fully and honestly informed before making the decision to sign the consent form. This is a significant decision for parents, considering Ireland is one of the very few countries in the developed world that still do not have a vaccine damage compensation scheme.

Two years ago when the Gardasil vaccination programme was discussed by this Committee, Dr. Colette Bonner from the Department of Health, noted the Committee’s concern that there is no vaccine damage compensation scheme. “There is an expert report which we are considering. I will convey the committee’s concerns both to the secretary-general and the Minister on this point,” she said.

We now know that Gardasil got CDC fast track approval and underwent a mere six months of human trial research. Subjects were only followed for 5-15 days in the safety studies, and only 1200 girls under 16 years of age participated (even though this is the target age for the vaccine). During these clinical safety trials paid for by Merck, 95% of the 'Placebo' injections contained the same toxic aluminium adjuvant as the vaccine itself, which resulted in Merck being able to claim that adverse reactions were not significantly higher than those of the Placebo group.

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4 & 5 In initial trials, participants only followed for 5-15 days from the last dose administered 6 months into trial http://www.merck.com/product/usa/pi_circulars/g/gardasil/gardasil_pi.pdf
What we also now know is that in a later 4-year clinical trial by Merck, 2.5% (1 in 40)\(^8\) of trial participants reported a serious adverse event* after taking the Gardasil HPV vaccine. In addition, 3.3% (1 in 30)\(^9\) also reported a new auto-immune condition.

*According to the FDA a serious adverse event must fit one of the following criteria: death, life-threatening, hospitalization, disability or permanent damage, congenital abnormality/birth defect, or the requirement to intervene to prevent permanent impairment\(^{10}\).

Given the current rate of incidence of cervical cancer in Ireland is only 13/100,000\(^{11}\), the benefits of this vaccine hardly appear to outweigh the risks.

The benefit, according to politicians and health authorities, is that 50 to 60 lives a year\(^{12}\) will be saved by the HPV vaccine in Ireland. However Health Technology Assessment Reports from other countries\(^{13}\) show that these statistics can only result from the combined effect of screening plus vaccination. However in Ireland these figures are being presented as the effect of vaccination alone.

The truth is that our girls will still require ongoing and regular pap smear tests, as protection from the HPV vaccine has not been shown to last longer than 8 years\(^{14}\).

**Worldwide concerns mounting for the safety of the Gardasil HPV vaccine:**

Gardasil has now been dropped from the childhood immunisation schedule in Denmark\(^{15}\) and replaced with an alternative vaccine. As of September 1st, approximately 1100 girls\(^{16}\) were being treated (or waiting to be treated) in five Danish regional medical centres for suspected Gardasil related conditions. Japan no longer recommends the HPV vaccine after conducting its own investigation into serious reactions\(^{17}\).

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\(^{8}\) See section “Serious Adverse Events in Clinical Studies”
(Note that Gardasil was being used as a placebo in this trial with "Gardasil 9" as the comparison vaccine).

\(^{9}\) See section “Systemic Autoimmune Disorders”

\(^{10}\) http://www.fda.gov/Safety/MedWatch/HowToReport/ucm053087.htm

\(^{11}\) http://www.ncri.ie/data/incidence-statistics

\(^{12}\) These “lives saved” figures have been presented in the Dail as the effect of the vaccine alone but in point of fact can only result from the combined effect of Screening plus vaccination.

\(^{13}\) Eg Austria: http://link.springer.com/article/10.1007%2Fs10389-009-0276-3

\(^{14}\) "Loss of 14% of measurable antibodies to HPV 16 after 8.5 years, supporting the belief that Gardasil boosters will be necessary before the 15 year threshold for actual cancer prevention":

\(^{15}\) Copenhagen Post article: http://cphpost.dk/news/doctors-question-denmarks-decision-to-switch-hpv-vaccines.html

\(^{16}\) Copenhagen Post article: http://cphpost.dk/news/danish-hpv-centres-flooded-by-ill-girls.html

\(^{17}\) http://ajw.asahi.com/article/behind_news/social_affairs/AJ201306150057
This month we have been told that Gardasil’s safety has been reaffirmed based on the results of an EMA Review which found no link between Gardasil and two specific medical conditions (CRPS and POTS).

Research Director and Consultant Dr. Jesper Mehlsen from Frederiksberg Hospital has studied many girls with suspected adverse reactions to the HPV vaccine. He has criticised the EMA, for not releasing the evidence of records and data, when submitting their early release conclusion. Dr. Mehlsen is now heading an independent investigation into the HPV vaccine, with results due out in April 2016. Speaking in June this year, he said "A realistic estimate is that one in 500 girls experience serious side effects".

Spanish doctor and professor of Public Health, Carlos Alvarez-Dardet from the University of Alicante, has initiated a petition against the HPV vaccine. He is a former President of the European Public Health Association (EUPHA) and was also an advisor at the W.H.O. He is now calling for an immediate stop to the vaccine.

Last month, researchers announced the results of a Canadian study to show the effect the HPV vaccine had on 170 teenagers who they followed for 4 years. They now question both the safety and benefits of the HPV vaccine, urging Quebec to halt HPV immunization until its alleged dangers have been independently investigated.

French MEP Michele Ravasi has compiled a large petition with hundreds of Physicians signatures calling for a moratorium on the HPV vaccine.

As parents we feel that the Minister for Health has a duty of care for 130 teenage girls suffering chronic ill health since the Gardasil HPV vaccination. However, he has consistently declined our requests for a meeting to discuss our daughter’s situation.

In a Private members Dail question to the Minister for Health in October (PQ: 36264/15), Deputy Maureen o’Sullivan asked “the reason parents are not provided a copy of the Patient Information Leaflet (PIL) prior to signing the consent form for the HPV vaccine”.

The HSE provided a response in the form of a letter from Dr. Kevin Kelleher, Assistant National Director of Public Health, which included this explanation:

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18 http://nyhederne.tv2.dk/samfund/2015-11-12-hpv-rapport-konklusionen-er-ikke-endelig
19 http://sanevax.org/gardasil-firestorm-in-denmark/
20 The epidemiologist Carlos Alvarez-Dardet, professor of public health at the University of Alicante and director of the Journal of Epidemiology and Community Health is the author of a manifesto published in the Spanish newspaper El País, giving the reasons why a moratorium on vaccination with Gardasil is imperative http://elpais.com/diario/2007/11/06/salud/1194303609_850215.html
21 https://www.academia.edu/16549844/For_a_moratorium_on_the_HPV_vaccine_Pour_un_moratoire_sur_le_vaccin_HPV
22 http://sanevax.org/france-are-hpv-vaccines-necessary/
“All the information provided to parents about vaccination is prepared from the available licensed documentation for each vaccine, the Summary of Products Characteristics (SPC) and Patient Information Leaflet (PIL). The information is presented in clear simple language and approved by the National Adult Literacy Agency so that it can be understood by all adults as the average reading age in Ireland is 12 years of age”.

So the official reason for the HSE withholding the list of known serious, debilitating and long term side effects from the HPV vaccine information literature is because “the average adult reading age is 12 years old”, and on that basis the content of these information leaflets is determined. I hope the absurdity of this logic is not lost on the Committee.

As an aside, I note that it was Merck Sharp & Dohme (MSD) who sponsored NALA’s 2007 Irish Health Literacy research project.23

There are some who would rather dismiss us as ‘Anti-vaccine’ parents, but we all gave our other children their vaccinations, just as we all signed the consent form for this one. We thought we were doing the best for them. Instead we signed away our girls future, and five years later they are still struggling.

Our lives were never the same following the Gardasil HPV vaccination of our daughters, with years taken from them, their parents, siblings and grandparents. We have been given no answers, guidance, or hope.

We live with the guilt of our decision to sign the Gardasil consent form every day, watching our previously healthy young girls struggle to get through their day, with our bags packed 24/7, in case of yet another emergency visit to the hospital.

Read some of our teenage girls stories here; http://www.regret.ie/victims 2.html

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23 https://www.nala.ie/support-us/corporate-sponsorships/msd#.VkyA-OHUdKs.facebook