Merck’s own clinical studies found -44.6% (negative) efficacy for women previously exposed to HPV infections.

Table 17. Study 013: Applicant’s analysis of efficacy against vaccine-relevant HPV types CIN 2/3 or worse among subjects who were PCR positive and seropositive for relevant HPV types at day 1. [From original BLA, study 013 CSR, Table 11-88, p. 636]

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Gardasil™ N=2717</th>
<th>Placebo N=2725</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N (subgroup)</td>
<td>Number of cases</td>
</tr>
<tr>
<td>HPV 6/11/16/18 CIN 2/3 or worse</td>
<td>156</td>
<td>31</td>
</tr>
</tbody>
</table>

Translation: Gardasil increases the risk of cervical cancer by 44.6% in women who were exposed to HPV prior to receiving the vaccine.
STUDY: 34% OF CHILDREN AGES 2-10 HAVE HPV INFECTION DUE TO NON-SEXUAL TRANSMISSION (BIRTH CANAL, CASUAL CONTACT)

48% of women ages 26-45 are infected, according to Merck’s package inserts. (24% have high-risk strain)

CDC recommends Gardasil for women until age 45 with no testing to determine HPV status.
**RESULTS: PRE VACCINATION PERIOD**

During the 1989-2007 period, the incidence of invasive cervical cancer declined continuously in all countries with pap screening.

These impressive advances are due to pap screening.
Cervical cancer increase in Australia following vaccine introduction.
Cervical cancer increase in United Kingdom following the start of the HPV vaccination program.
Cervical cancer increase in Sweden following vaccine the start of HPV vaccine campaign.
Cervical cancer increase in Norway following the beginning of HPV vaccine campaign.
Figure 4: Comparison of the trends of incidence of invasive cervical cancer during the first years of vaccination (2007-2012). The incidence of cervix cancer improved in France and worsened in countries with large vaccination uptake.