

# HPV vaccines: 15 doctors denounce the risks of conflicts of interest

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*Vaccination against human papillomavirus (HPV). AFP*

**Fifteen health professionals object to the recent campaign to vaccinate girls and boys against HPV. They denounce the influence of the pharmaceutical industry on the promotion of HPV vaccines, urge the authorities to resist it and call for a moratorium on vaccinating with the HPV vaccine.**

On March 20, the "Call of the 50" struck hard. Academies, colleges, medical societies, unions, medical personalities and patient associations called on the authorities to increase vaccination against human papillomavirus (HPV), and to extend it to boys. The press release of the 50 found a resounding echo in the press. "More than 20 media outlets covered the subject," said LJCom on Twitter five days later. The agency that was behind the media uptake, specialists in communication and influencing health care decisions, counts among its clients companies that produce HPV vaccines.

Why was there such a coalition demanding the vaccination of girls and boys? "We are doctors, each in different specialties, more or less concerned with cancer and HPV vaccination.

We see that France, one of the major developed countries, has catastrophically low rates in terms of vaccination coverage and recommendations. In the United States, Australia, England, and Scandinavian countries.... girls and boys are both vaccinated," explains pediatrician François Vié Le Sage, coordinator of the AFPA's vaccinology group and Infovac expert.

***"More than a thousand women die each year from cervical cancer".***

Noting that this is a public health priority, and that "more than a thousand women die of cervical cancer every year", the pediatrician reminds us that vaccination is "the real prevention" and the screening pap smear, "an important second option, has not been sufficiently implemented in France.", It could "perhaps, be abandoned in a few years, if we achieved 90% vaccination coverage." HPV causes several cancers: cervix, pharynx (tonsils), anus, vulva, vagina, and penis. "Of the 6,300 cases per year, half are women, and the other half are both men and women," the doctor says.

While only 20% of young French women are vaccinated for HPV, the academic societies wish to "restore scientific truth" and "increase trust in these active and very well tolerated vaccines". "Gardasil and Cervarix prevent 70% of infections responsible for HPV-related cancers, and Gardasil 9, 90%. Tolerance studies around the world show that the benefit is clearly in favor of the vaccine," says Dr. Vié Le Sage. "In Australia, with massive vaccination coverage of girls and boys over 12 years the prevalence of HPV-related cervix, anus and precancerous cervical lesions have collapsed. There is also an indirect effect on unvaccinated boys, who have fewer lesions due to these sexually transmitted viruses. This is because many girls, and more and more boys, are being vaccinated. This country plans to eradicate the viruses responsible for cervical cancer within 20 years."

***"We must vaccinate more girls and start vaccinating boys, under the same conditions of reimbursement. »***

Fearing that France might be running "against the tide" on "this vaccination that prevents preventable cancers", the 50 learned societies call to mobilize a "formidable and historic victory against cancer". They also support Minister Agnès Buzyn in her decision to refer the matter to the High Authority for Health (HAS) on the relevance of a recommendation for universal vaccination. "We must vaccinate more girls up to the age of 19 and start vaccinating boys, under the same conditions of coverage by social security and mutual insurance companies," the doctor adds. With 40% of people hesitating to vaccinate in France, should mandatory vaccination for these vaccines be considered? "The policy in France is more to convince than to coerce. How to apply the needed pressure? In the case of vaccines for children under 2 years old, it is prohibited to enter daycare and school without proper childhood vaccines. It seems difficult to interrupt a high school student's schooling because he or she is not vaccinated against HPV. As for imposing fines, the Minister does not support this approach."

***"I attend industry meetings because they are the ones who make the product. »***

When asked about the weight of conflicts of interest in the health field, the pediatrician replied: "I have links with industry, necessary for my expertise, but no personal enrichment. Would you have your car repaired by a garage that has no connection with Renault or Peugeot, and does not know what they manufacture? Sometimes I get paid for conferences by the companies. I go there, especially in Europe, because it is essential to see what is being done elsewhere.

I attend a few meetings of the companies because they are the ones who manufacture the product. I want to know what they do and how they do it. But scientific studies remain the main sources, for me. Meanwhile, my office is closed and I am on zero income. The industry are guilty for, among other things, a lack of transparency during the controversy over hepatitis B and the the Mediator scandal. But since the 1990s, there has been such a high level of control that manufacturers cannot write a line or take any action without the approval of the Ministry. You don't see any commercial radio or TV spots advertising a vaccine. All funds paid to doctors must be declared on the [Transparency Health Database website](#). Conflicts of interest, i. e. when a physician personally enriches himself by promoting an industrial product, are clearly to be avoided."

***"There are uncertainties about the efficacy and safety of these vaccines. »***

In contrast to the Call of the 50, some doctors and pharmacists are opposed to widespread use of HPV vaccine and consider that a moratorium on these vaccines "is necessary". All very committed to their independence from the pharmaceutical industry, these 15 health professionals signed a fully-referenced minority report stating that there are "major uncertainties about the efficacy and safety" of HPV vaccines. Considering that the industry's influence has been omnipresent on these products since their introduction on the market, these doctors denounce the Call of the 50 whose signatories have not respected the obligation to declare, personally and individually, their links and conflicts of interest. This Public Health Code legislation, which is poorly followed, was created following the Mediator case. The 15 signatories of the minority report hope that the Minister of Health "will be able to resist the expected media pressure."

***"We are dreaming this is a revolutionary product, though it's not. »***

Rémy Boussageon is a general practitioner and university professor in Lyon and a member of the scientific committee of the National Council of Teaching Generalists (CNGE). This was one of the few academic societies that refused to sign the Call of the 50 considering it to be "a lobbying operation", explains the doctor, who signed the minority report in his own

name. "We are dreaming that this is a revolutionary product though it is not," reacts Dr Armel Sevestre, in Rennes. Health blogger and general practitioner in Mantes-la-Jolie, Jean-Claude Grange says he is "terrified that they presume the effectiveness applies to the entire population". For him, the message of the 50 is clearly "an authoritarian and paternalistic approach, where people are treated in a way that is good for them in spite of themselves".

Pharmacist and hospital practitioner in Cholet (Maine et Loire), Amine Umlil recalls the arrival of Gardasil in France in 2007: "I was surprised that in February, Minister Xavier Bertrand announced the reimbursement of this vaccine while the HAS transparency commission was still evaluating the benefit-risk ratio and had not given its opinion." "Miracle vaccine not yet reimbursed by social security", was the headline in the women's press. [The Minister reportedly gave in to media pressure following the major communication campaign launched by Sanofi Pasteur MSD at the end of 2006.](#) On the island of La Réunion, where Gardasil was launched in advance, Doctor Philippe de Chazournes thinks he is the first Frenchman to have "asked the embarrassing question". President of an independent medical training association, he presents himself as a general practitioner and expert skeptic.





***"Why is there a vaccine if cervical cancer is not a public health problem?"***

When in November 2006, a professor of medicine who had "participated in the development of Gardasil" came to the island to present the vaccine as "revolutionary" for the women of Reunion Island, Dr. de Chazournes was puzzled. "Why is there a vaccine if cervical cancer is not a public health problem?" With an advertising blitz in newspapers, on TV, and in all pharmacies... Gardasil was propelled as a major innovation against cancer. "It is not a vaccine against cervical cancer, but a vaccine against certain HPV viruses related to this cancer," the doctor recalls. Under his leadership, the Regional Union of City Doctors of Reunion Island financed a quarter page in "Le Monde" on 8 September 2008 to publish a counter-advertisement.



DES MEDECINS GENERALISTES VOUS INFORMENT :



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LA VACCINATION CONTRE LE CANCER DU COL DE L'UTERUS

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- 1/ QUE SON EFFICACITE AU DELA DE 5 ANS N'A PAS ETE DEMONTREE
- 2/ QU'ELLE NE PROTEGE pas CONTRE tous les types de VIRUS RESPONSABLES de cancer
- 3/ QUE SA TOLERANCE A LONG TERME EST INCONNUE

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LA MEILLEURE PREVENTION du cancer du col de l'utérus  
RESTE SON DEPISTAGE PAR UN FROTTIS tous les trois ans.

LA DETECTION d'une éventuelle anomalie permet alors de la GUERIR  
AVANT MEME QUE LE CANCER NE SE MANIFESTE.

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[www.urml-reunion.net](http://www.urml-reunion.net) puis 

Campagne d'information, entièrement financée par les généralistes de l'Union Régionale des Médecins Libéraux de la Réunion.

His activism prompted several calls from one of the vaccine manufacturers: "The uptake in Reunion Island is not taking off!" A meeting of the departmental council of the Order of Physicians concerning the "slander campaign orchestrated around Gardasil" was said to provoke the "dissatisfaction of many colleagues". A well-known expert, president of an academic society, travelled to the island to defend the virtues of the cervical cancer vaccine and stifle controversy. "In 2006, I was an easy prey because I was quite isolated. Today, there are more of us. We are irritants because we are credible," says the doctor. Philippe de Chazournes, former correspondent of the French High Authority for Health (HAS), explains that this independent institution "has never been very supportive of HPV vaccines".

At the Cholet Hospital Centre, Amine Umlil organizes public meetings on the vaccine. When he discovered the Call of the 50 in the press, he decided to provide balanced information on these vaccines for his readers. "I published data before our meeting on Gardasil because the issue was urgent. I considered that the Call of the 50's report was neither objective nor truthful, that it did not present the proper risk to benefit information, and that it did not mention the possible uncertainties, as required by the Public Health Code and the regulations ordered by the French Drug Agency in 2018."

## **The efficacy of the cancer vaccine has not been demonstrated in clinical trials**

"Uncertainties" is the central problem pointed out by these 15 professionals: although the vaccine prevents certain precancerous lesions, its effectiveness against cancer has not been demonstrated by clinical trials. Prescrire, the independent journal that enabled pulmonologist Irene Frachon to break the Mediator scandal, pointed out in March that the evolution from a precancerous lesion to cervical cancer is rare (0.3% of infections) and occurs after an average length of time of nearly 30 years (most infections are transitory). The effectiveness of the vaccine is thus merely "hypothetical". In addition, it stated that the benefit of the vaccine "for vulvar, vaginal and anal cancers" (rare cancers) "is not established by clinical data", and that its ability to reduce the risk of severe injuries in men has not been demonstrated.

"If the vaccine is effective on precancerous lesions, it would not be illogical for it to have a benefit on cancer," says Professor Bousageon. But the formal evidence is not there yet, as everyone says." What about the Australian data? "These are statistical models. This study, as well as the one just published in Scotland, are not good evidence. Relying on observational data to claim victory is not consistent with the principles of evidence based medicine\* when it comes to proving the effectiveness of a treatment. Just because the Lancet or the British Medical Journal publishes these studies does not mean that they are automatically reliable. These are arguments of authority." The professor points out that the overall prevention of cervical cancer is not only from the vaccine: If it is necessary, it is not enough. Many factors, tobacco, the age of first sexual intercourse, the number of partners, socio-economic conditions and screening are all factors at play. We also forget to promote the use of condoms, which are

essential to protect against sexually transmitted diseases. These elements should be discussed in consultation with the patient, who can then make an informed choice. It is all the more important to discuss these matters as the benefit and risk of these vaccines are uncertain."

***"If the vaccine is 30% effective, 100,000 women will have to be vaccinated to save one life per year. »***

To assess a preventive therapy, the doctor prefers the "population approach": "Let us consider that out of 30 million women, 1000 die each year from cervical cancer. If the vaccine has an efficacy of 30%, 300 lives are saved. This means that 100,000 women must be vaccinated to save one life a year! Then we have to ask ourselves how this could be justified from an economic point of view. In addition, if the benefit of the vaccine is low, the risks of a serious adverse event, even if rare, can outweigh the benefit." While most of the adverse reactions observed (many of which are not reported) are relatively mild and transient, it is plausible that this vaccine may expose the patient to an increased risk of Guillain-Barré syndrome. "A rare but serious, and potentially fatal risk," says the hospital pharmacist, who refers to the [CNAMTS independent study and the report of the ANSM Technical Committee on Pharmacovigilance of 2015](#). If the 400,000 girls concerned chose to be vaccinated, "there would be 4 to 8 more girls with Guillain-Barré syndrome every year because of the vaccine, with one death every 2 to 3 years. Every year, 1 or 2 women would remain permanently disabled."

According to Prescrire, the replacement of Gardasil by Gardasil 9 raises a critical point. First, because this new generation vaccine does not provide any additional benefit, but also because the dose of adjuvant (aluminum) that it contains doubles the risk of a severe reaction at the injection site. In the context of "vaccination hesitancy because of fears of a serious adverse events", the medical journal concluded last year: "instead of painful vaccinations accepted in adolescent girls, it is much more useful to focus on other public health measures that can reduce the severity of cervical cancer, such as organized screening in adult women."

## **The vaccine anticipated the launch of organized screening by 12 years**

Organized cervical cancer screening has been demanded by health professionals for 30 years. The cervical smear examination is the main factor in the rapid decrease in the incidence and mortality related to cervical cancer since the 1980s which is now 12th place among cancer deaths in women. A few weeks before Gardasil was launched in 2007, [a cost/benefit analysis by the Technical Committee on Vaccinations](#) (CTV) recommended introducing organized screening before introducing vaccination. This was wishful thinking. Once commercialized, the vaccine set back the launch of organized screening by 12 years, announced in January by Agnès Buzyn.

Although recommended in combination with the screening smear, HPV vaccination appears to benefit from a fast track since it was licenced. And this, despite doubts, reluctance,

and the cost to the community, especially if the government initiates routine vaccination of both girls and boys. The 15 signatories of the minority report calculated: "The pre-tax cost of vaccines alone would represent €1.9 billion for the first two years and €180 million annually once established". In short, widespread vaccination would also be successful business venture, particularly for the Merck laboratory, [which has seen large profits since the end of 2018, mainly thanks to sales of an anti-cancer drug and Gardasil](#). HPV vaccines represent a major opportunity for the American giant, which is recovering from the loss of Vioxx, its "king of blockbuster", whose global withdrawal in 2004, and compensation to victims, cost billions.

***"Between 2012 and 2018, the signatories to the 50-member appeal received €1.6 million from vaccine manufacturers."***

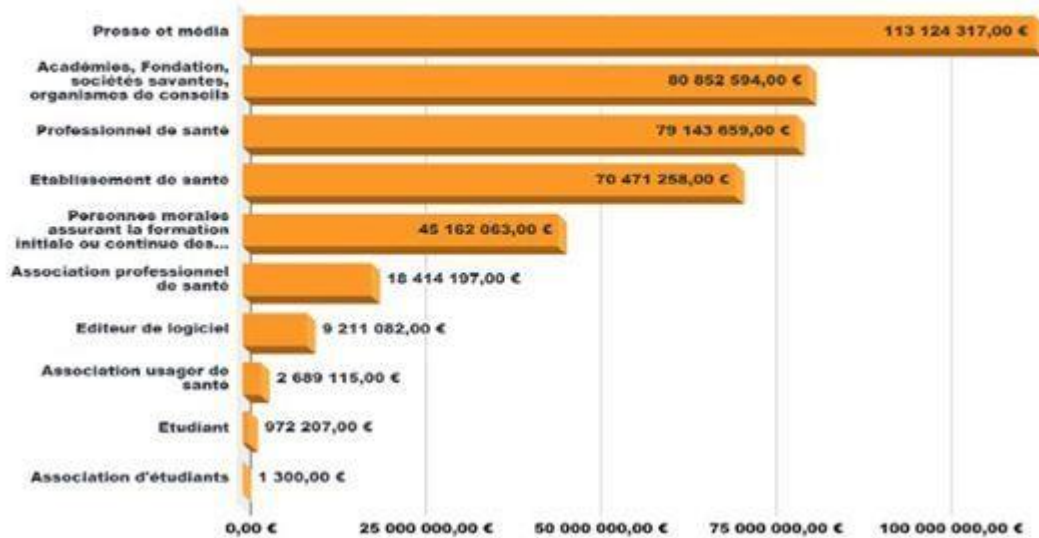
Is the industry's hand behind the March 20 media campaign? "To inform their fellow citizens", the 15 doctors included in their minority report [an analysis of the links and conflicts of interest of the signatories of the Call of the 50](#). As the Health Transparency Database is not very useable and poorly indexed, they used [Euros for Docs](#), a tool that makes the data reported by manufacturers much more workable, especially considering that "a significant proportion of the contract remunerations declared in the database are kept secret" and that payments are under-reported. "Underestimated amounts", experts "without conflicts of interest paid indirectly by industry", patient associations that are "empty shells", "industry-funded medical training"... The research carried out by these doctors also reveals "a certain financial strength" behind the Call of the 50. According to the study, "between 2012 and 2018, all signatories received €1,611,066 from the manufacturers of HPV vaccines (Sanofi Pasteur MSD, MSD and GSK). A sum divided between professionals (223,765 euros) and structures (1,387,301 euros)".

## **The press and the media, primary target of the pharmaceutical industry**

Of great interest is the research that reveals, over the same period, the amounts allocated by these three laboratories to all health stakeholders for the promotion of all their products: 420,041,772 euros. In the breakdown of their investments, we see that the target "press and media" is far ahead in first place, with 113,124,317 euros. Academies, learned societies and foundations come second.



### Montants alloués par les 3 producteurs de vaccins HPV à l'ensemble des acteurs de la santé (2012-2018)



Amounts allocated by the 3 HPV vaccine producers to all health stakeholders. Euros For Docs

## The Call of the 50: "A house of cards supported by strong industry ties and conflicts of interest"

"It's a huge lobbying campaign," says Dr. Sevestre, who compares the Call of the 50 to a "house of cards." It is a large structure whose structures are quite fragile, but which holds together thanks to strong industry ties and conflicts of interest. By failing to declare their conflicts, the signatories of the Call of the 50 do not allow the audience to have a critical look at the information delivered. A person who doesn't have time to look or who is used to trusting will think that it is impossible for all these people to be wrong," says the doctor. "What's extraordinary is that the companies don't have to show up anymore," says Dr. Grange. "Before a product is launched, we have already gathered and convinced those we have designated as the future world's leading experts in pathology. This happens in the "boardrooms of the medical medical committees set up by the companies to bring together experts to reflect on the long-term strategies in infectiology, antibiotic therapy and AIDS research. The discussions are recorded, and examined by the marketers. The next step is to infuse these strategies with ideas for product marketing development. These experts are then used as speakers at post-market conferences to popularize articles showing the effectiveness of the product."

*"The 10 pharmaceutical giants have invested 2.6 times more in marketing than in research."*

A new pharmaceutical era where marketing is king? This was already demonstrated in 2005 by [a socio-economic analysis conducted by the Université de Québec à Montréal](#) at the global level: "Between 1996 and 2005, the ten "Big Pharma" companies spent \$739 billion on marketing and administrative expenses compared to \$288 billion on research and development expenses.

**VIII) Frais de marketing et d'administration versus frais de recherche et de développement pour les dix dernières années (1996 – 2005) :**

Marketing et Administration	=	739 milliards U.S.	=	257% ou 2,6 fois
Recherche et Développement		288 milliards U.S.		

***"What is happening with Gardasil is true for other health products."***

Faced with such a powerful influence, drained by a very complex network of conflicts of interest, one wonders if critical thinking about a health product could be stifled or discredited? "The international medical system has become frightening. Abroad, many authors publish critical analyses. In France, where academic power is very strong, there is an absolute vacuum," deploras Jean-Claude Grange. "What is happening with Gardasil is true for other health products. The tragic thing is that people are losing confidence in medicine and taking refuge in non-professional health therapists. This is not good for the care of our patients," says Dr. de Chazournes.

Among the 15 signatories, there are physicians active in social media, analyzing the scientific literature and debating the relevance of public health policies. "Their work is prolific! That is somehow what one would expect from independent professionals. Perhaps France lacks an agency that, without resorting to conflicted experts, could analyze scientific data according to a rigorous, evidence-based methodologies. Believing that citizens are ahead of institutions, the professor adds: "We can have expertise without having a conflict of interest with industry. This was a weakness in the 1980s because we were not considered experts. Today, it is becoming a strength in the eyes of the citizens. Our message is even more credible because we have no financial interest in promoting or opposing a treatment."

Restoring citizens' trust in the health sector is also something our public health authorities need.