House of Parliament

October 3rd 2011

The truth about Gardasil and anti-HPV inoculation against cervical cancer.

Debate cum press conference.

Organized and directed by Dr. Philippe de Chazournes, GP in Reunion Island and chairman of the association "Med'Ocean", Dr. Jean-Pierre Spinosa, gynecologist, cancer specialist, obstetrician, part time lecturer at the Faculty of Medicine, University of Lausanne and Mrs. Catherine Riva, journalist, author of *One Injection Too Many* and Dr. Joël Pelerin, GP in Réunion Island, a member of the Association "Med'Océan".
With the participation of Dr. Gerard Bapt, MP, Chairman of the enquiry commission on the Mediator medicine.

Anti-HPV inoculation under scrutiny.

Dr. P. De Chazournes:

TC 0047 Good morning everyone and good morning to you, Mr. MP. Thank you for letting us use this room in this highly symbolic building : the House of Parliament.

0058 We are not here by chance but following years of investigation, individual and collective actions.

0105 For the next 10 to 15 mn I propose to make clear the reasons for our being together here. This presentation will be followed by three interventions :

- By Dr. Jean Pierre Spinosa, sitting on my left
- By Dr. Joël Pelerin
- And by Mrs. Catherine Riva.

0132 First of all let me remind you of an important item in the *Public Health law Book* : the obligation made to members of the medical profession, when speaking in public about health products, to declare possible conflicts of interests with businesses and laboratories who manufacture, sell or advertise these products.

0200 This does not mean answering by a mere yes/no the question : do you have conflicts of interests?

I believe this deserves some explanation, taking the example of what actually happens with the AFSSAPS or with the French Health Authority.

0212 Over the last five years, have you been paid (personally or in the name of an association you are active in) a salary, cash money, fees, stock options or received presents, been given travel expenses, paid Congress fees, or been given medical equipment…or do you have shares in a private business which could benefit or loose from your personal statements or from information you have made public?

0243 The person is supposed to answer yes or no.

0246 if you answer YES, you will be asked to name the reasons why you have given a positive answer. Your declaration will be annexed to the document.

If you have answered NO to the initial question, what will be noted is “no conflicting interests declared by the person”. What is misleading is “no conflicting interests declared by the person” and not “the person has no conflicting interests”.

And if you have wished not to answer the question, what will be noted is “no declaration of conflicting interests”.

0313 Let me remind you that conflicting interests are by no means illegal. What matters is to know who we are dealing with and this is only to make sure the information is clear and fair.

It is important to know how come we are here today, October 3rd 2011 and to know that the fight for the cause I advocate, that we advocate, that some of you in the room, advocate, individually at the start then collectively, has, in fact, started a few years back. Thanks to Internet it became possible to unite into a group what, at the start, were individual opinions.

A short history of the problem as presented in the press)

0348 In Réunion Island it all started in 2006…November 2006. We were then given the opportunity to inoculate our teenagers before it could be done in metropolitan France. This was presented as a piece of luck.

0403 Of course, seminars were organized for those who were to prescribe the inoculation. And who were they? Mostly GPs and gynecologists, but mostly GPs.

0413 All of a sudden, in chemists' shop windows, in cinema halls, on TV, everywhere, mention was made of this anti-HPV inoculation.

0425 As I have just mentioned conflicting interests, let me confirm that I have no conflicting interest whatsoever.

0431 How come things have reached that state? Why all this advertising for an inoculation which can be said to be "a market out of nothing" as explained in the book *An injection too many*?

0447 At the start, the position we defend was put forward within the *Union Régionale des médecins Libéraux de la Réunion*, of which I was then a member. But I stood alone in my defense of our arguments. So, we paid for an add to appear in a "minor national paper", *Le Monde* which people could read in the underground. The message read "despite massive advertisement for the inoculation against cervical cancer, do you know :

- That its efficacy has not been proven beyond five years
- That it does not protect against all type of viruses
- That its long term effects are not known".

0525 This was in 2008…not in 2011!

0529 This insert appeared on page 3 of *Le Monde*.

What can the general public, who reads the national press, believe?

0541 Who speaks the truth? Health authorities, laboratories?

0544 What about the *Ordre National*? That is an interesting question. Their conclusion in a letter dated October 1st 2008 was " the campaign advertising for this vaccine was launched by the public health authorities and it seems difficult, to day, to go back on it".

What does this really mean, when reading between the lines? It means that everyone knew there was a problem but once the machinery had been started it was impossible to stop. This dates back to October 2008.

0614 Then there was an open letter sent to Professor Harousseau, member of the French Health Authority, asking him to reconsider the situation, another letter sent to Xavier Bertrand, then Secretary of State for Health.

0625 What did we do this morning? This very morning, a small group of us were sitting in your seats, for a sort of "consensus meeting". We had invited the Chairman of the Scientific Committee on vaccination, and the Chairman of the *Haut Conseil de Santé Publique*. Neither bothered to come.

0642 But Dr Sales, director of the *Evaluation économique de la HAS* (Director of the Economic evaluation of the HAS) attended our meeting. We put our arguments forward to him, those arguments you are about to hear in a few minutes.

A brief reminder of what cervical cancer really is …

- Quite a few viruses are responsible for this cervical cancer, it stands as the 8th cancer among women under 40 years of age, with 3000 new cases per year. A few weeks ago, The INC (National Cancer Institute) published an estimate of slightly less than 3000 cases for 2011 with less than 1000 deaths. The accurate projection for 2011 is 800 deaths. We all agree that this is 800 deaths too many.
- During their lifetime, over 80% of women will be affected by HPV – there exist many types of HPV, about 40. 30% will be affected within the year following the first sexual intercourse, but practically all of them will eliminate it within two years of being infected;
- If the HPV resists, it can evolve into pre carcinogenic states which, in turn, can evolve into cervical cancer.

0655 On the INCA report, you can see that both the curves indicating the frequency of new cases and the mortality rate have been regularly decreasing over the years, starting long before the inoculation started.

0758 Today, our fight is neither against inoculation at large nor against laboratories. I am and we are fighting for quality, with the DEMING Wheel, which is a quality reference for the HAS, encouraging us to check what is being done and always improve upon the quality of what is produced…

0816 I am no expert, or, possibly, an expert in quality, like other members of the HAS, attending this conference.. But I definitely am an expert when it comes to questioning.

This will be my conclusion and I now turn to Jean Pierre Spinoza, who will introduce himself…

0830 Dr Gérard Bapt : To my knowledge, the laboratories did their own advertising and not the public authorities. The *Ordre des Médecins* seems to say "by the public authorities". I'd like to see the letter to know what Public Authorities they refer to. Possibly, they are the public interests of the labs.

I forgot to mention my own conflicting interests. I have many personal links, if only because I have many friends who are GPs and specialists, who hold responsibilities in or just work for labs. I am regularly invited, as an MP in charge of Public Health and Social security problems, to seminars, luncheons and breakfasts. But of course, I never received any financial retribution.

0910 Dr Jean-Pierre Spinoza: Mr. MP, I hope my intervention will provide answers to some of your questions.

Let me introduce myself, so that everyone knows who I am, although my Swiss accent betrays me.

I specialize in obstetric gynecology. In Switzerland we have a specialty referred to as "specialist in gynecologic surgery". This means that, unfortunately, I have to operate upon cervical cancer. I am a part time lecturer at Lausanne University and co-authored the book, *An Injection Too Many* with Catherine Riva.

0946 : I have no conflicting interests, direct or indirect, to confess, respecting every point mentioned by Dr. De Chazournes.

Before I am asked the question, let me tell you beforehand that I have no anti inoculation sympathies and that I myself used to prescribe this vaccine until a friend, mother of a girl who had been recommend this inoculation asked me the question which is at the heart of this conference.
As you'll see, I had to seriously question myself when I realized I had not familiarized myself enough with the information sheet when I used to prescribe the vaccine.
1033 The documents upon which my conference rests are all official documents, open to the general public as long as one is prepared to read them.
What I am going to give you is not my own personal opinion. It is nothing but a review of the literature published on this topic. Do not tell me it is what I think, it is not what I think, it is what has been published.
1059 The plan I propose to follow during my intervention is fairly simple but the points I deal with are essential in order to avoid mischievous or not to the point questions.
1112 Which is to say:

- From the start one has to know what where the laboratory estimates regarding the expected efficacy of the vaccine and the authorities who patented it.
- Regarding statistics, we have to agree together on what is a pertinent (relevant) corpus, otherwise statistics can be interpreted any way one likes. So, what corpus is pertinent to judge the vaccine's efficacy?
- There is one very important point, essential to me : we have to agree on whether we have to analyze only those lesions resulting from HPV 16 and 18, constitutive of the vaccine or all lesions (point 4) resulting from absolutely all viruses.

1159 Let's forget about strains 6 and 11 because we are arguing about preventions of cervical cancer and pre carcinogenic stages that go with it and strains 16 and 18 are those involved in the carcinogenic evolution. Strains 6 and 11 are linked to non malignant lesions, such as condylomata and perianal warts..etc. which have little to do with carcinogenic lesions.

1230 The laboratories told us about the expected efficacy of this vaccine : I did not find out myself and you did not invent it. It all sprang from a good idea. The initial postulate was that HPV rarely evolve into pre carcinogenic lesions (which can also regress) but can at times result in cervical cancer. The research hypothesis was that since 70% of pre carcinogenic pre carcinogenic lesions are caused by strains 16 and 18, if we eradicate strains 16 and 18 - you can see them here, on the left (**TC 1310**)we should end eradicating 70% of the total number of lesions. This simple mathematical calculation only works if the vaccine is efficient on all lesions resulting from strains 16 and 18.

1330 The expected scenario is that if one can produce a vaccine which can eliminate all strains 16 and 18, there will be no lesions associated with these viruses. That indeed, was an excellent idea. Consequently, on should reduce by 70% the number of lesions which is equivalent to the number of lesions associated with this vaccine.
1351 Let me insist on this point: what matters is the total reduction of pre carcinogenic lesions and of cervical cancer - let us put them together; This reduction must be the only criteria to

evaluate this vaccine. Any criteria taking into account the reduction of lesions causes by strains 16, 18 being of secondary interest or even of no interest whatsoever, as I shall explain later.
1420 So, what happened with your authorities, with American, Swiss, Italian, European authorities ? Exactly the same thing : they concentrated on the reduction of lesions caused by viruses making up the vaccine. One can read in every text produced by the HAS references to lesions 6,11,16,18;6,11,16,18; 16,18..I can go on 16,18;6,11,16,18, etc.

1452 If you can eliminate all these strains and be left with lesions caused by other viruses, then the battle is won. At least partly because you eradicated 70% of pre carcinogenic lesions and of cervical cancers.
1508 Let me show you a table that Catherine Riva and I have drawn up of prospective randomized studies of phase 3, the only ones which can, from statistics, assert whether the efficacy of the vaccine has been proved or not. The capacity to say YES, it is efficient or NO, the efficacy has not been proven. There are no other studies. Do not ask me why I haven't taken into account "such a study which…". All and every studies are there.

1540 There is a first essential point to keep in mind: we all expected a reduction within the group of inoculated persons (the laboratories, the health authorities, the GPs..). Of course, the level of reduction would vary according to the prevalence of HPV 16 and 18. What was the percentage of these HPV 16 and 18 among lesions which varied between 55 and 70%.
1609 What matters then is the total percentage of lesions caused by all viruses.
1614 20000 subjects were submitted to four randomized studies. Here they are. They have been numbered : 5,7,13 and 15. For the specialists number 13 will become Future 1 and number 15 will become Future 2.

1628 What is a randomized study? What is a lottery? I apologize to my colleagues but I feel the journalists need an explanation.
You understand that when one asks people to take part in a random study, one gets all sort of subjects. The next step is to make homogeneous groups because you cannot compare a group of women who have been given three shots of the vaccine with a group of women who have been given only one. You cannot compare women who, from the start, were affected by viral strains with who were not. Let us compare what can be compared.

1700 What is true of all medical studies, not only for the Gardasil, is that when you try and compare what can be compared you end up with two main groups:

- One group, representing what I call the ideal corpus, the "per protocol" one. It is made up of women who are free of all four viruses and, most important, who have followed the protocol which means they been given all the vaccine injections. Last essential point : we have been able to follow them regularly because, if they cannot be followed, one cannot draw conclusions about the efficacy of the vaccine.
- On the other side, you have the other groups, which also can be of interest because it allows – on your left - (TC **1739**) you to see what the vaccine should give ideally while

on your right you can see what will happen “in real life” to the vaccine when one inoculates a population which is not “relevant” because protocols are not respected.

1756 And why is all this so important? Because the initial hypothesis, which was correct, was that Gardasil was not meant to cure but to prevent. Hence, it is but normal to find a reduced efficacy among girls already affected by the virus, but the vaccine was not for that.

1818 It is obvious that the efficacy will be less among the general population than among the ideal group, the one which followed the protocol.

1829 Let us insist on the table which makes clear why this “per protocol” population is important. It is the only population in which the three doses have been injected. At the start the women concerned were not affected by the virus and each of them could be followed regularly. This is the group we are going to concentrate on. The other ones can be “biased” which means they do not offer enough certainties to come to definite conclusions.

1852 Second point : let’s go through the literature dealing with the population, for ”per protocol” population.

1859 Now, to loop the loop, how can we confirm that this model, the one without addition of other HPV, is the good one? It is rather simple. The vaccine will be useful if we can reduce this (**TC 1910**) – you have already seen the slide. This would be the ideal scenario we all wish to see happen.

1919 On the other hand, if this is what happens (**TC1922**), then the reduction, even the destruction, of viruses 16 and 18 will have been useless in terms of prevention, of public health and as regards information given to our young patients. It would be useless because what would be gained on one side would be lost on the other.

1945 I drew up this last slide, with circles increasing and decreasing but you can read in papers issued by the authorities that they took this problem into account. What they say is that one has to be certain that Gardasil will not increase the incidence of other HPV types. If it did so, you merely substitute one type of illness to another. It means you have achieved nothing.

2018 Third message to keep in mind: to prove the definite and global efficacy of this vaccine, one needs a complete study and not just one bearing only on 16 and 18 viruses.

2030 What interests me and which is the fundamental criteria is to find out whether this reduction has been accompanied or not by an increase in other lesions. When one goes through the randomized studies, seeking the numbers which should appear in this little square (TC **2045**) one finds absolutely nothing while these were the only relevant data. The numbers have deliberately not been published.

2056 These answers can be found in the documents issued by sanitary organizations, notably FDA who asked for them. Under table 23 (TC **2113**), lost among numbers showing a fantastic 100% efficacy, one finds study 015. You can read it with me. Efficacy analysis against serous pre carcinogenic dysplastic lesions 2 and 3, or more, which are cancers induced by all HPV strains. It looks like what we are looking for in the population fitting in with the “per protocol” conditions.

2142 What is really happens is that Gardasil does prevent the appearance of dysplastic lesions at 16 and 18.This is true. But, being on favorable environment, the lesion is likely to develop

because of the presence of other **oncogene** viruses (because 16 and 18, as you know are two viruses regularly found among the 15,16,17). Because of those **oncogene** viruses not targeted by the vaccine you can see (TC**2210**) whatever study or population you take into account, whatever the end point there is no proved efficacy of the vaccine (with two exceptions) in the total reduction of the number of lesions. There is no proved efficacy of the vaccine in the total number of lesions.

2230 You also know that the innoculation of any product is established on the basis of random studies which are supposed to compare a product one wants to market – in this case the Gardasil vaccine – with a neutral substance referred to as "placebo".

FDA, as you can see at the bottom of their Internet site, describes placebo as an inactive substance, comparable to an active agent precisely to avoid placebos problems, but which has no medicinal value. It is a substance we can call inactive substance.

2302 In the forthcoming Future 1 – a controlled randomized study against a placebo – 2000 patients have been given a placebo. Here down bellow (TC **2310**) we go on saying it is still a placebo. Well, the placebo is everywhere, you see it here…

2317 There is however a small problem with the placebo.. When you analyze very carefully those studies, you realize that in the forthcoming Future 1, what is called a placebo is not a neutral substance. It is an aluminum containing substance. They admit it themselves. They call it (TC **2234**) "aluminum containing placebo".

2237 You can look in all innocuousness studies conducted on this product one which would have compared the active substance, the vaccine itself, against a neutral substance. We have a vaccine made of (TC 2357):

- **Imunogenic** proteins from viruses 6,11,16 and 18.
- Aluminum
- Sodium chloride
- Some L. **Histamine**
- **Polysorbate**
- Sodium borate

And the placebo made up of the same things.

2418 The only conclusion we can reach is not that the vaccine is not more dangerous than the placebo but that the vaccine is not more dangerous than the substance it was compared to. Which means that the vaccine is not more dangerous than its adjuvant !

2434 Every one of us, members of the medical professions, media people who relay the information, hospital specialists.. has to be very careful with the information given to the population because we all are in a very responsible position. And as you know we live in an increasingly judiciary society. We have to assume responsibility when members of the medical professions prescribe the vaccine. As a speaker here, I also assume a special responsibility, telling you all this. My conviction is that we have to be honest : sooner or later, according to what the future holds in store, we could well be brought to account.

2512 Thank you for your attention.

2513 Dr. Philippe de Chazournes : Thank you so much, Jean-Pierre. While Jöel Pelerin is getting ready, I'd like each of you to introduce himself individually, or mention if you represent an institution or an institute and mention possible conflicting interests if you belong to the medical profession.

2525 Dr Damienne Castaigne: I belong to the medical profession. My name is Leca-Castaigne. For many years I was in charge of a ward at Gustave Roussy and as an oncologist surgeon I have operated upon – and I am glad to know that you have operated upon – many cervical cancers.

What I fail to understand is your position against this vaccine. I agree that one can be against all that advertising done by the labs. But when you demonstrate, and this is what people wonder about, everybody – and I have no conflicting interests, I no longer prescribe, I am retired, and if I attend the "women and cancer" medical conference, possibly paid for by the inviting committee and I don't know where they get their money from. I personally have no conflicting interests.

2608 So, what I do not understand is that we know it is 16 and 18, the majority of cases in France and in most countries, we'll see later in South America and elsewhere. We know that's it. And the questions one asks are : will this vaccination not give rise to other VHP viruses? Well, you are very clever to have demonstrated with two little circles and three studies that you definitely know that HPV against HPV 16 and 18 will bring about other vaccinations.

2641 Today, the medical community, vaccine specialists, infection specialists, viruses specialists , keep asking themselves whether it is going to work or not and no one has any certainty. We are all aware of the problem but it is difficult to accept all this. This is what I had to say.

2658 Dr. Spinoza : Thank you, Madam, for your comments but I believe you misunderstood me. I am not telling you that Specialist in viruses,….I am simply telling you that when one gives the go ahead for a product, there are some rules to be respected, and you know it as well as I do since you were in charge of a ward at Villejuif. These rules are those of statistical studies.

2721 : What the virologists or the epidemiologists or the whole world for that matter think is of little importance. From the moment theses studies do not prove the efficacy, whatever people think and whoever they be, the efficacy has not been proven. When efficacy has not been proved, one starts another study but does not draw conclusion.

2742 Now, when you tell me that our conclusions are based on three or four studies only..I challenge you to find other ones. These are the three random studies. There is no other one. Authorizations to market the product were based on these studies. In fact, you and I, the virologists and epidemiologists are debating about the same things. This document, I'll let you have it with pleasure.

2809 Dr Damienne Castaigne : Oh yes, with pleasure.

Dr Jean-Pierre Spinoza : With pleasure but I am surprised you don't know them.
DR Damienne Castaigne: So detailed and showing that the vaccine is of no use on pre carcinogeic lesions and lesions…
Dr Jean-Pierre Spinoza : caused by all viruses..
DR Damienne Castaigne: caused by all viruses… that is what I cannot admit from two slides; I'd like you to send them to me and we can all discuss that together…
Dr Jean-Pierre Spinoza: Madam, I am sorry but..
DR Damienne Castaigne: Well, I might be wrong…
2828 Dr Jean-Pierre Spinoza : Madam, I perfectly understand that you cannot admit it. I am going to send it to you out of courtesy..
DR Damienne Castaigne I do hope so !
Dr Jean-Pierre Spinoza : What I cannot understand is that being an expert at Villejuif you didn't know those results.
2836 DR Damienne Castaigne : Of course we knew them but…
Dr Jean-Pierre Spinoza : If you knew them, why do you ask me the question?
DR Damienne Castaigne: Yes..it's easy to argue.
Dr Jean-Pierre Spinoza : But, I do not argue..
DR Damienne Castaigne: One would believe your are on your own, you want to .. do again those studies..
Dr Jean-Pierre Spinoza : But I am not doing again anything…
2848 DR Damienne Castaigne: Send them on…let us discuss it again. This is of no importance…I do know that 16 and..
Dr Jean-Pierre Spinoza : Well…
2852 DR Damienne Castaigne : Just a minute. I know that we can say that on 16 and 18, the vaccine has proved efficient ; don't try and get at me

A voice in the assistance : This has already been sais a thousand times…
DR Damienne Castaigne : OK, OK.
2902 : It remains to be seen if those two slides, the ones with all viruses included are really correct and if they are going to be used again. That's all. If you have that, it's ok.

The truth on Gardasil and anti-HPV inoculation against cervical cancer. Third part.

2920 : Dr De Chazournes: I suggest Dr Bapt speaks and then it will be Dr Pelerin's turn.

2924 : Dr Bapt : As for myself, I didn't know Dr Spinoza. I meet him today. On the other hand I have known Dr De Chazournes since I was a member of the Enquiry Commission on the flue

and I highly respect him. If you wish so, I can communicate the Emails he exchanged with the technical Committee on vaccination and with the DGS, at the time massive doses of vaccine were being ordered. He kept telling them : the flue came to Réunion and it proved not worse than any other, even less so.. What's more, it is over with and you still want to vaccinate the population. Do not join the vaccine craze..
3001 From that time, I give credit to Dr De Chazournes.
3008 The second point is a decree published by the AFSSAPS in the *Journal Officiel* dated October 2 2010. For once reactive, it forbade an advertisement for Gardasil on the ground that this add presented Gardasil as a vaccine against cervical cancer. If AFFSAPS said so in 2010, it means there is some truth in it.
3027 Dr De Chazournes : Well, thank you. Now, to Dr Pelerin.
3031 Dr Joël Pélerin : Good morning. My name is Joël Pelerin and I am GP in Réunion island. I have no conflicting interests. I am simply a GP. With, however, a small difference : for a long time I was an chemist. It was a family tradition : every one became an engineer, and so did I. But I wanted to practice medicine and I became a GP. For over twenty years now I have been practicing in Réunion … and I still have habits from my previous training. Whenever I get a new medicine, I like to check if it presents a reliable efficacy.

The first thing one does with a medicine is to compare it with a placebo. Well, dam it, such studies do not exist in this case. At least there is no mention made…

I say to myself : well, that's incredible. They sell a medicine and there are no comparative studies with a placebo for the "per protocol" group, the ideal group!

So, I spent nights looking for an answer and I found exactly the same FDA texts Dr Spinoza mentioned : same tables, same thing altogether. I spoke about that around me…I spoke to Dr de Chazournes and here I am. If I am here it is not because I am anti vaccine but because I looked for a proof of the efficacy of this vaccine against the placebo in the ideal group.

3157 Here are the statistics for Europe: 2364 cases of cancer where studied. Among them 2058 were HPV affected, which represents 87% - and not 100%.

Out of those 2058 HPV affected cases, there are 68% serotype 16 and 7% serotype 18. Out of all cancer affected patients , HPV 16 represent 57 % and HPV 18 6%. The total is 63%.

3231 Let me give you this illustration. Here we have all cervical cancers studied on women affected. (TC **3237**). Here is the lot of those HPV affected and this (TC **3240**) represent those affected by HPV 16 and 18. They only represent 63% of all cervical cancers in Europe.
3248 One of the little publicized consequence is the false feeling of safety created by vaccination according to which vaccination equals safety. Most women believe that cervical smears are useless once vaccinated.

3301 Cervical cancer is a treacherous one. It can remain dormant for a long time, giving no clinical signs. When women eventually consult because of such signs as persistent bleeding or ureter compression – the diagnosis is often definite because it is too late while the carcinogenic lesions revealed by smear tests can all be cured.

3323 When I talk the matter over with colleagues, they tell me…..it's not fully efficient but even if its efficacy is limited, it remains that it is a vaccine against cancer, and that is better than nothing. I say no to this. The danger is that vaccinated women feel protected and no longer go through the smear tests. You'd have to keep reminding them over the next twenty years, and this will not be done. Imagine telling them : "you have been vaccinated but go through the smear tests". They will not do it precisely because they have been vaccinated, they feel safe and will consult only when they present clinical signs : too late! Hence it is likely that the mortality rate will increase as was mentioned as early as 2007 by the CTV (Technical Committee on Vaccination);

3404 Well, it seems to me, I say, it seems… that among the definitely affected patient, the efficacy becomes negative. Not only it is not protective but quite the opposite : there are more lesions due to viruses 6,11,16 and 18 among the vaccinated group.

3438 This is not the case in the "per protocol" group, where, by definition, women tend to be more naïve regarding the virus. It is in our daily practice since it is said the vaccine can be inoculated within a year of the first sexual intercourse. In some countries, they even propose to vaccinate up to the age of 40 or 45.

3438 Among those who are but slightly infected, PCR positive + but sero negative – the efficacy rate collapses down to only 31%. Among those who are seriously infected PCR + seropositive, the efficacy turns negative : minus 25%. This clearly proves that there are more lesions in the Gardasil group than in the placebo group.

3503 We speak about cervical cancers, but in the case of venereal warts one feels the same is true. For instance, for those who are seropositive or PCR positive, the efficacy is also negative.

3515 You can find this on the FDA website but it was never published. This was never investigated, it is not to be found in any paper.. . it does not speak in favor of the vaccine!

3524 When they learn, in 15 years time, that we knew but kept quiet, what shall we tell them?
3530 There are colleagues who tell me : .. there is an Australian study..quoted by the lab, heard of on the radio : that's it Gardasil is efficient, it was proved in Australia… it was widely publicized..it proves the efficacy among girls under 18 year old.

3545 Vaccinating one million women has saved 21 lesions among the under 18 but resulted in 800 lesions among other women. The global result is an extra 790 lesions among the

vaccinated ones compared to the others. All that for that (TC **3609**). The paradox is that we end up 790 extra lesions among the vaccinated group. Of course, no one mentions this..

3619 Fortunately, this is a bad study, otherwise it would be a tragedy. But there must be some truth in it, and once again it confirms that the virulence has been increased..?
3630 Thanks a lot, Joël. Now, to Catherine Riva.

The truth about Gardasil and anti-HPV inoculation against cervical cancer.

Fourth part

3643 Catherine Riva : let's get back to facts
In 1997 Merck asks for a patent for its monovalent vaccine, the one which is in protocol 005, briefly mentioned by Jean-Pierre Spinoza.

3658 In 2000, it submits a proposal for the quadrivalent vaccine : the Gardasil as we know it today. And Merck make another request : not only would they like to patent a quadrivalent vaccine but they ask for something which has never been done before : the "fast track" habilitation for this vaccine.
A "fast Track" is a method developed in the US. Originally it was devised for the first anti AIDS medicines. The argument was that because there was nothing existing to help Aids afflicted patients, medicines with less proven results, would be made available.

3736 But never in the whole history of medicine, has a vaccine been allowed the fast track procedure; Merck asked for a fast track for the Gardasil. The FDA gave the green light and Merck started working on a fast track patent. One can see it all went very quickly.

3747 In 2002, studies are underway on a "fast track" : these are the only studies from which one concludes that the treatment is efficient.

3753 In 2006, the VRB PAC met, voted and decided that the authorization to market this vaccine could be given.
It is important to say how things happened, it all went very quickly.

3806 About the anti HPV vaccine, the question one must ask when examining a study is : what is the good (relevant) end point ?Which is the good clinical criteria ? And what is the good primary outcome? What is it we have to prove in the study and which are the good secondary outcome ? It all comes to establishing a hierarchy in what we want to prove.

3826 What is interesting in this document is that it stipulates from the start that if one limits the primary outcome to those HPV targeted by the vaccine (is it efficient against lesions or

infections caused by those two HPV?) it gives an exaggerated result of the efficacy of the vaccine. If the end point had been illnesses caused by all HPV viruses, the results would have been very different.

3901 The question Jean-Pierre Spinoza asked, the Health Authorities asked it as far back as 2001 and they made it clear that the ultimate objectives of an anti HPV vaccine were to prevent all types of cancers associated with HPV viruses.
This is when the FDA made a huge rhetorical mistake, at the origin of the present situation : they said "It will also be important, as a secondary analysis, to evaluate the efficacy of the vaccine against all lesions caused by HPV viruses".

3943 The vaccine was patented and prospective random studies were no longer possible because this is just not possible once a vaccine has been patented. It is clear that once a medicine has been patented, once it has been accepted that it is useful you cannot experiment on it and conclude : it's fifty/fifty. Either you get an injection which is useful or you get an injection which is useless ! In terms of medical ethics you just cannot do it.

4007 The huge mistake was to start work on the "fast track" basis because cervical cancer cannot be compared to AIDS, because we could already prevent it. The primary outcome should have been the vaccine efficacy on all types of lesions and the secondary outcome should have been to check lesions in the per protocol group to make sure they were not caused by viruses 16 and 18 among vaccinated women.

4028 What remains to be explained is why did the FDA accepted such shilly-shallying . Why did they say : look, as long as we don't have these information, we suspend the fast track ?

4137 Dr Philippe De Chazournes : Thanks a lot Catherine. What happens is that today we are working on Gardasil but we could equally be working on antyhypertensive , hypocholesterolaemic , anti-Alzheimer… We hear more and more about these products...in service medical training is at the root of the problem, not to mention the initial training since the pharmaceutical industry is more and more present in universities and faculties… This could be another debate.
Now, I turn to you Dr Bapt.

4103 Dr Gérard Barpt : When the Gardasil problem leaked out it was at first because of possible conflicting interests regarding the functioning of the HAS commission on the prevention of cervical cancer. This is when , on the occasion of your visit for at audit , you informed me about this problem and gave me documentation I studied closely. I wrote to the previous chairman of the HAS, professor Degos. When I learnt that many participants didn't come this morning I sent a note this morning to the general director for the AFSSAPS….I also sent a note to Mr. Van Roekeghem, Director General of CNAM, asking him what I had already asked for in the Mediator case : an epidemiological pharmaceutical study.

4152 We now have a corpus large enough to know what happened to these people in terms of risks.
4157 I, too, was struck by what many families have written to me about the suffering of their daughters. One told me : I sent my daughter for a medical certificate to take part in sporting activities. The GP convinced us to get her inoculated…Two weeks later, the first manifestation of an auto immune illness appeared.
4216 One can only notice that despite warnings, criticism about conflicting interests, commercial interests, the Mediator remained on the market for years and years. As regards vaccination, nothing will change.
4234 Dr Philippe De Chazournes: Thank you all for coming. Just another piece of information. I also invited Sanofi laboratory, by registered letter. They acknowledged receipt of the letter, but since then, no news! Sanofi thought it useless to attend our afternoon meeting.

4253 C. Riva : Most of all we worked on the Gardasil. Phase 3 studies on Cervarix, the Patricia studies, were made public only four months before our book was due to come out. This explains that we worked a lot on Gardasil and little on Cervarix. All statistics and information given today are about the Gardasil, the Sanofi product. We also insisted on Gardasil because it started this blockbuster approach to vaccination.
That's what is new with Gardasil. Previously, vaccines didn't bring in any money. They were bypassed by other research and development programs. It is the first time a vaccine brings in over a billion dollars a year. That's why we have little to say on Cervarix , although there are problems (the use of a new type of adjuvant); Medical literature like the *Arznneitelegramm* have brought to light facts regarding the way studies were conducted.
This explains why Philippe de Chazournes thought fit to limit the laboratories representation to Sanofi.

4428 Dr. Catherine Dormard : Dr Dormard Catherine…In his letter Dr Gérard Barpt, MP, mentions accrued checking. I would like to know if you heard about any checking at all..because the problem is with side effects, I think….and I'd like to know if the corpus of inoculated women was drawn up, was followed and on which criteria. Do you have the answer?

4452 Dr Gérard Barpt : I do not think so…this is what I ask for in the second part of my letter : that a corpus be organized.
4500 **Dr. Catherine Dormard :** If Dr De Chazourness and myself stood against cervical cancer detection it was mostly because of conflicting interests. In the end, we did manage to get the assurance that the corpus of those thousand women who had been inoculated would be followed;
4524 You have to really keep this up

4526 **Dr Philippe De Chazournes :** I do not know what will be the outcome of these two meetings. What is certain is that health authorities dream of extending this inoculation to even younger girls.;9 or 8 year old..and to boys. And why not past 25 years of age? The aim is

to inoculate half the earth population with a vaccine which is not really very useful, at least among our populations.

Video now in French, soon in English and Spanish.
French transcript by
English version by DR. MICHEL POUSSE, Senior lecturer, University of la Réunion .
English dubbing (male voice).....
English dubbing (female voice).....