



American University of Armenia

Հայաստանի Ամերիկյան Համալսարան

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QUALITY, EFFICACY AND TRANSPARENCY IN THE MEDICAL RECOMMENDATIONS AND PRACTICES OF NATIONAL HEALTH INSTITUTIONS AND ACTORS IN THE MEDICAL WORLD.

Examples of the H1N1 crisis and the vaccine “Gardasil”.

WHO AM I ?

- ❖ A whistleblower in the medical world: I used a methodology and a critical view about medical recommendations.
- ❖ If a medical recommendation seems wrong, I investigate and I alert the health authorities.
- ❖ I'm a field expert and a doubt expert.

PUBLIC DECLARATION OF INTERESTS

- ❖ According to the French law, all the medical actors that speak out in the media or in conferences/seminars have to state their PDI.
- ❖ If not, it's punished by law.
- ❖ Most of the medical world actors in France don't do it.
- ❖ In order for the situation to change, each one has to do it, here is mine (short version) :

"I have no ties or conflict of interest with the pharmaceutical industry, neither I nor anyone in my family"

WHAT IS A CONFLICT OF INTEREST?

Definition :

“A person is in a conflict of interest situation if she is in a relationship with another in which she has a moral obligation to exercise her judgment in that other’s service and, at the same time, she has an interest tending to interfere with the proper exercise of judgment in that relationship”

❖ **The conflict of interest affects judgment, alter the research and information, and eventually the decisions.** (Formindep, French Medical Association).

❖ It’s not forbidden to have conflict of interests, but everyone has to know it.

PLAN

1. QUALITY OF MEDICAL RECOMMENDATIONS

2. EFFICACY OF MEDICAL RECOMMENDATIONS

3. TRANSPARENCY OF MEDICAL RECOMMENDATIONS

Common Thread:

MEDICAL RECOMMENDATIONS AND ESPECIALLY PRESCRIPTIONS

From two examples, Gardasil and H1N1.

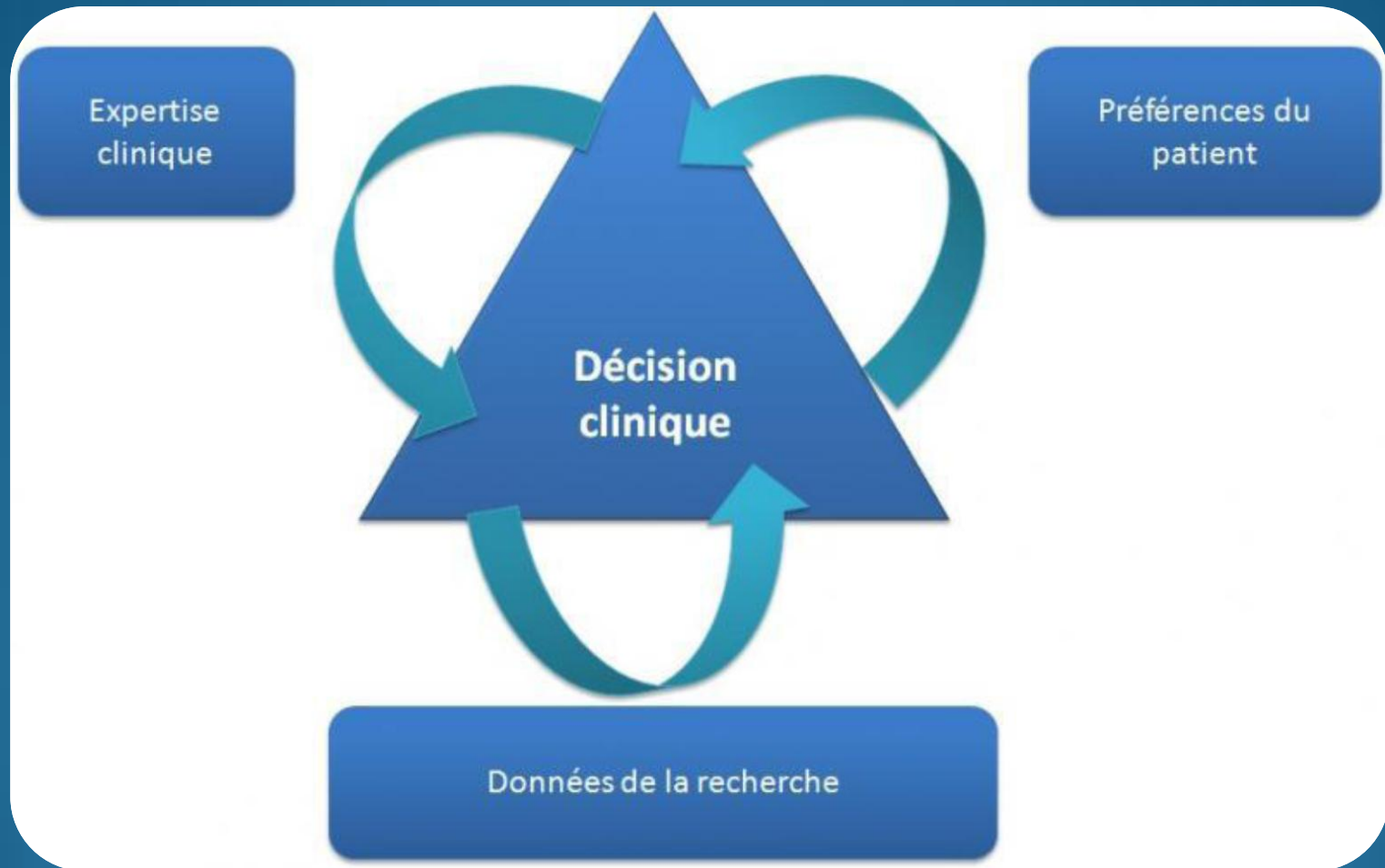
The medical prescription

- The prescription, drug or not, has almost become a political act
- It can be a self-interested act against public interest on one hand or a critical and evidence-based act, concerned with public health on the other hand.
- There is a singularity of the medical consultation between the caregiver and the patient, based on the trust that the patient attaches to his caregiver

1. QUALITY OF MEDICAL RECOMMENDATIONS

The validity of the prescription must rely on evidence-based medicine methodology that is primarily what has been shown by reliable, independent studies, and adapted to the patient, his personality, his individuality and his clinical condition.

EVIDENCE-BASED MEDICINE



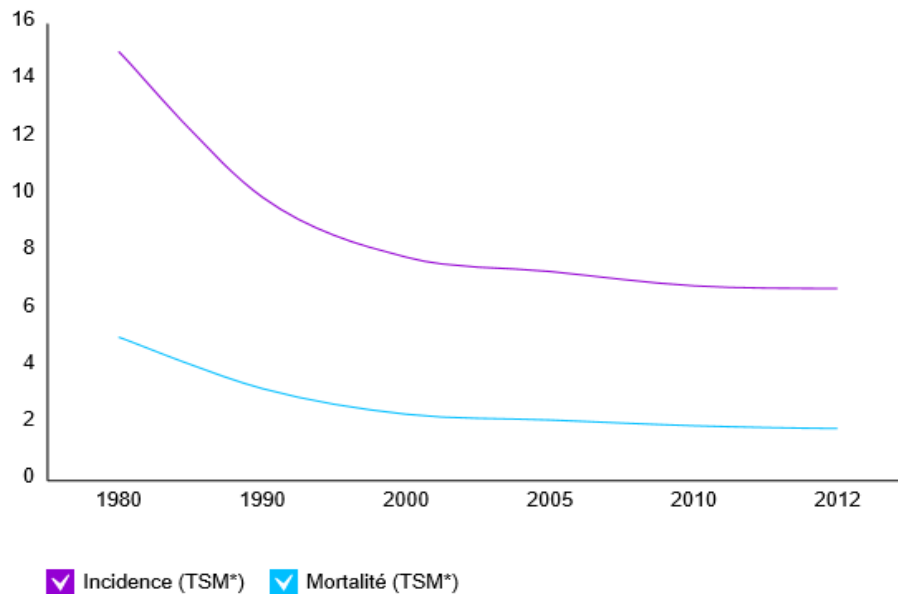
For the vaccine Gardasil:

- Inadequate methodological criteria for the studies
- No publication of negative results.
- Efficiency unproven vis-à-vis all the HPV virus responsible for cervical cancer.



2. EFFICACY OF MEDICAL RECOMMENDATIONS

1. IS THERE A PROBLEM? Example: *The evolution of the cervical cancer from 1980 to 2012 in France*



* : taux standardisés monde pour 100 000 personnes-années

Sources : Estimation nationale de l'incidence et de la mortalité par cancer en France entre 1980 et 2012. Partie solides

2. IS THIS A PROBLEM CREATED FROM NOTHING?

- Monday morning depression
- Hyperactivity disease
- Mourning...

3. IS THE COST OF TREATMENT IJUSTIFIED?

- Gardasil is the most expensive vaccine in France today
- Millions of doses of the vaccine against the H1N1 were purchased by France but have never been used. They were eventually sent to Africa...

3. TRANSPARENCY OF MEDICAL RECOMMENDATIONS

Throughout the course of the prescription, actors act with sometimes competing interests. The scenario for the placing on the market of a drug and its removal often seems to follow a similar process over time.

Process:

1. Fabrication of a drug (secret process)
2. Marketing of a drug (using media, special advisers for doctors paid by companies..)
3. Decision of medical experts in National Health Institutions (with often conflict of interest..)
4. Selling of the drug
5. First suspected case with averse effects
6. Media scandals
7. Court cases in justice

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 Coordination :
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 Charles Nahmanovici
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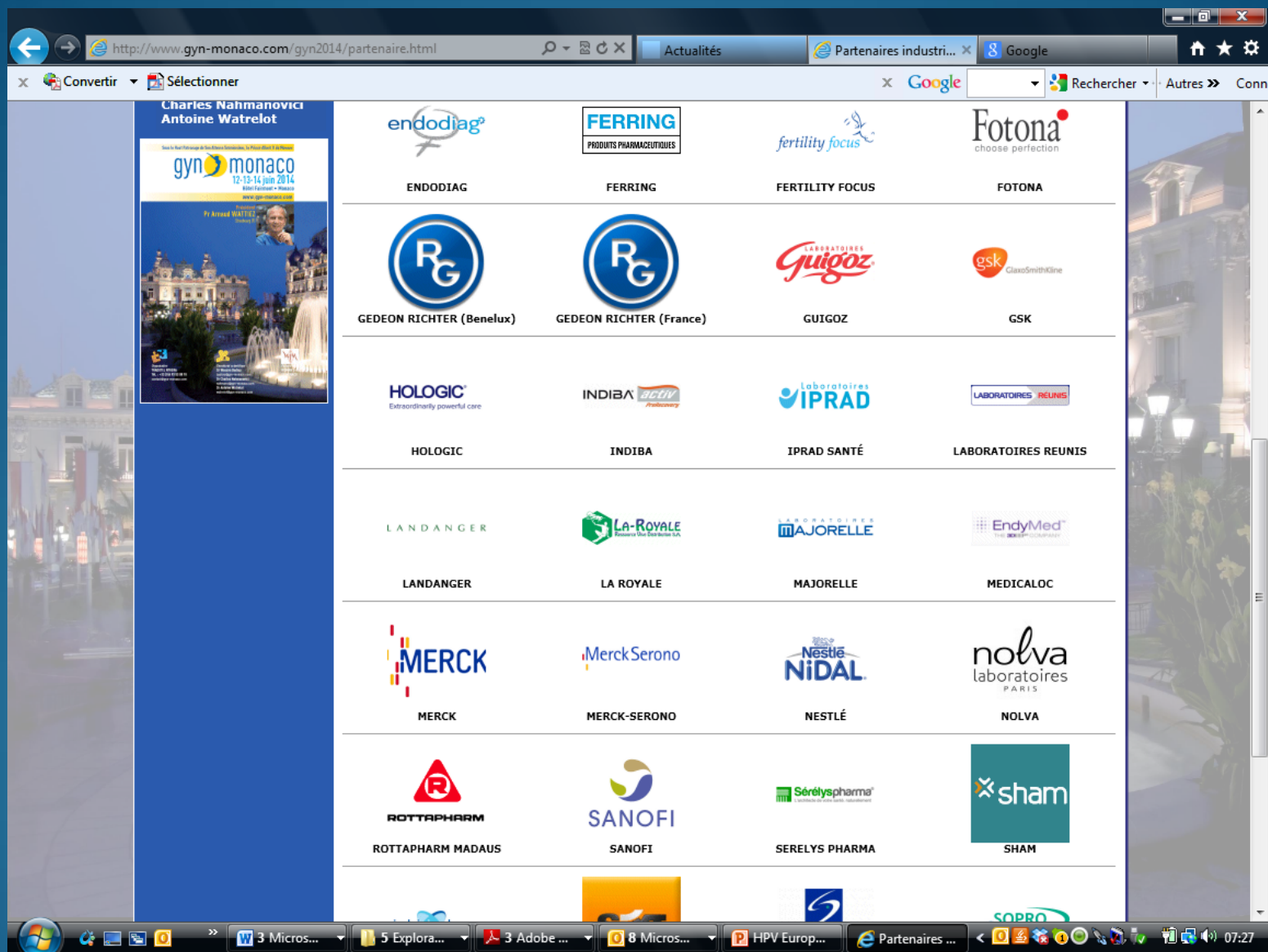
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We need:

- ❖• Reporting and disclosure of conflicts of interest of medical recommendations and scientific articles authors, and all other sources involved.

- ❖Public Expressions of interest for all actors of the medical world who speak out (media, conferences ..).

- ❖Full transparency and disclosure of conflicts of interest of experts serving on national and international health organizations (eg, HAS, ANSM, EMEA, FDA, WHO).

- ❖Full transparency on funding of studies used in medical recommendations

CONCLUSION

MEDICAL INDEPENDENCE AND QUALITY OF CARE

- They need to be practiced every day
 - They need to be built
- They need to be declared publicly
- They need to be protected and financed

Thank you for your attention

If you want to know more about the topic:

Prescrire, French Medical Magazine (*with no funds from pharmaceutical companies and with an English version*) :

<http://english.prescrire.org/en/>

Med'Océan, my website, part of the website is in English:

<http://www.medocean.re>

The Cochrane Collaboration, on Evidence-Based Medicine:

<http://www.cochrane.org/>

The Formindep : webmaster@formindep.org

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