

World Health Organization Vaccine Recommendations: Scientific Flaws, or Criminal Misconduct?

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ABSTRACT

While much information concerning World Health Organization (WHO) recommendations on vaccines, particularly against hepatitis B, remains secret, there is sufficient evidence in the open literature to suggest scientific incompetence, misconduct, or even criminal malfeasance. The benefits are overstated and toxicity greatly understated. Influenza vaccine recommendations falsely imply that the available vaccines could help prevent avian influenza.

After the universal campaign of vaccination against hepatitis B was launched in France in September 1994 upon the recommendations of the World Health Organization (WHO), a criminal inquiry was opened because of the demand by the relatives of people, some of them children, who had died after being immunized.

Having been commissioned as a medical expert witness by the French judge, I have spent thousands of hours on this subject, and had access to dozens of confidential documents. Although my reports are still secret by court order, a number of my findings were leaked after being transmitted to the litigants. Thus, it is possible to find a significant echo of my observations in published data. The main points of this paper were taken from an open letter sent to WHO's Director General in Nov. 2005, which remains unanswered.

Hepatitis B Epidemiology

In February 2004 I read correspondence from an Indian colleague¹ on the fallacies of the data disseminated by WHO about the epidemiology of hepatitis B in his country. Although not well informed about the health situation in India, I was struck by the fact that the mechanisms of the deception as described in this letter (lack of references, inappropriate extrapolations, and gross exaggerations) were exactly comparable to those I observed in my own country. The results were also the same: a plea of "experts" to include hepatitis B vaccination in the national vaccination program, in spite of its cost and its unprecedented toxicity.² There are stunning fallacies underlying this plea for universal vaccination.

In a paper published no less than 10 years after the start of the "information" campaign launched at WHO's instigation, two eminent representatives of the *Direction General de la Santé* (DGS: our French Centers for Disease Control and Prevention) blandly recognized that there was up to a sevenfold uncertainty about the French figures for the incidence of hepatitis B.³ One may wonder whether the average American citizen would take seriously the result of a U.S. census showing that his country had between 250 million and 1.75 billion inhabitants. How is it possible to rely on "experts" who, in assessments involving huge financial costs as well as hazards threatening newborns or very young children,^{2,4} apparently accept uncertainties that would be viewed as ludicrous in demographic counts?

In the same paper,³ the authors admitted without the slightest irony that the French figures about chronic liver diseases were simply

extrapolated from the U.S. reports. Yet no great epidemiologic expertise is needed to grasp that extrapolating U.S. data on chronic liver diseases to the country of the *Beaujolais nouveau* or *Châteauneuf du Pape*—in other words, to the country that probably has the highest rate of alcohol-induced diseases—probably does not meet the requirements of scientific rigor.

More recently, an American expert working for WHO claimed that 250,000 people die of hepatitis B in India, based upon a model stratified for geographic region and income groups. Indian skeptics, however, suggested that this alleged model never existed and that the initial figures given should be "refined" towards far less alarming assessments.⁵ Such practices—there are similar exaggerations about the French situation—would normally be considered fraudulent, yet they triggered no reaction from WHO when they were made public.

Despite the blatancy of the falsifications, and in the face of the serious adverse health consequences of the French campaign,² the Indian government has, more than 10 years later, decided to include hepatitis B vaccine in its national program.⁷ This decision is explicitly based on WHO assessments!

Hepatitis B Vaccine Safety

Meanwhile, WHO or its "experts" go on publishing reassuring statements⁸ based upon an explicit reference to a safety study⁹ that, according a public communiqué of February 2000, even the French agency decided to "discard." An unfortunate misprint in Table 2 of this study—uncorrected to my knowledge—allows the authors to halve the clear increase of multiple sclerosis in vaccinated teenagers and young adults. Such an error would normally lead one to suspect fraud. In the promotion of the hepatitis B vaccination, WHO has evidently served merely as a screen for commercial promotion, in particular via the Viral Hepatitis Prevention Board (VHPB), which was created, sponsored,¹⁰ and infiltrated by the manufacturers. In September 1998, after the serious hazards of the campaign had been given their first media coverage in France, the VHPB organized a panel of "experts," whose reassuring conclusions were given extensive media coverage as reflecting WHO's position. Yet some of the participants in this panel had no expertise beyond being employees of the manufacturers, and the vested interests of the rest did not receive any attention.

Five years later, in order to put an end to the public concerns raised by the first leaks of my own judicial reports, the French agency prepared an "international consensus conference," without even informing the researchers who documented the unusual hazards of this vaccine,¹¹⁻¹⁵ or the person whose work sparked it (this author). Its conclusions have nevertheless become a major element of WHO (and the CDC) argumentation about the safety of hepatitis B vaccine.

To analyze the preliminary results of the cornerstone investigation by Hernan et al.,¹⁶ the organizers invited R.T. Chen from the U.S. Centers for Disease Control and Prevention (CDC). Chen has published dozens of papers denying most of the concerns about vaccine safety, and is a coauthor of a study¹⁷ that reached results opposite to those of Hernan et al. An excellent way to obtain a "consensus" from a conference is to limit attendance to those who already agree with the desired conclusion. There was not even a

pretext of democratic debate for the sake of appearances. P. Van Damme, organizer of the Cannes international congress on Action Toward Control of Hepatitis B as a Community Health Risk,^{1 8} which exerted a paramount influence on subsequent French (and world) vaccine policy, was first presented at this “international consensus conference” as an “epidemiologist, WHO Collaborating Center for Control and Prevention of Viral Hepatitis, Antwerp.” Later, his affiliation was listed as “public health and social medicine, WHO Collaborating Center for Control and Prevention of Viral Hepatitis, Antwerp University.” It would be crucial to understand why French parents had to be kept in ignorance of details given to *The Lancet* readers within the same period, namely: “many authors were principal investigators in vaccine trials and acted as advisers to pharmaceutical companies.... The chairman of the group, P. Van Damme, has done vaccine trials for several vaccine manufacturers.”⁹

It was even more damning that in an interview in a widely circulated French journal,^{2 0} Beecham’s business manager claimed with outrageous cynicism: “We started increasing the awareness of the European Experts of the World Health Organization about hepatitis B in 1988 [emphasis added]. From then to 1991, we financed epidemiological studies on the subject to create a scientific consensus about hepatitis being a major public health problem. We were successful because in 1991, WHO published new recommendations about hepatitis B vaccination.” When the immunization campaign was in full swing, the French official “experts,” including those of the DGS, did not hesitate to participate in the hype under the form of “medical” publications coauthored with this salesman.^{2 2}

It is sad news for people everywhere in the world that WHO’s experts need manufacturers’ salesmen to become “aware” of significant health problems. Moreover, the manufacturer did its best to prevent publication of this stunning confession, according to the journalist responsible for this interview.

Avian Influenza

This new awareness of WHO’s questionable behavior, and of its tragic consequences in terms of health and financial costs, occurs in the context of another scandal, again involving WHO: avian influenza. It appears that, under the lame pretext of increasing the manufacturing potential, the manufacturers managed to induce WHO’s experts to recommend influenza vaccination, whereas it is plain that this immunization would have no protective effect against avian influenza.

In both situations, the method was the same: First, create a false alarm about the inefficiency of targeted vaccination in the case of hepatitis B^{22,23} and about the necessity of increasing the manufacturing process in the case of avian influenza. Next, induce WHO to plead for measures based upon misleading recommendations to lay people, stating that everyone was at risk of hepatitis B or implying that influenza was such a serious disease that it required a mass vaccination.

Specialists are currently challenging WHO for turning a veterinary issue into a medical one and thereby preventing national agencies from taking appropriate measures concerning animals,^{2 4, 2 5} which probably would have been far more efficient in limiting the spread of epidemics. Additionally, the figures concerning fatalities related to influenza vaccination,^{2 6} together with the problem of underreporting, suggest that up until now, irresponsible influenza vaccination has killed far more people than avian influenza.

Conclusions

There is an urgent need for an independent inquiry about the process leading WHO to recommend measures favorable to drug makers’ interests, even when they are based on scientifically

irrelevant or falsified information. It is time to differentiate between the interest of world health and that of WHO’s experts.

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REFERENCES

- Puliyel JM. Plea to restore public funding for vaccine development. *Lancet* 2004;363:659.
- Girard M. Autoimmune hazards of hepatitis B vaccine. *Autoimmun Rev* 2005;4:96-100.
- Antona D, Levy-Bruhl D. Epidemiology of hepatitis B in France at the end of the 20th century. *Médecine et Maladies Infectieuses* 2003;33(Suppl A):34-41.
- Comenge Y, Girard M. Multiple sclerosis and hepatitis B vaccination: adding the credibility of molecular biology to an unusual level of clinical and epidemiological evidence. *Med Hypotheses* 2006;66:84-86.
- Puliyel JM. Policy analysis of the use of hepatitis B, *Hemophilus influenzae* type B, *Streptococcus pneumoniae*-conjugate and rotavirus vaccines in the national immunization schedules. *Health Econ* 2004;13:1147. Author reply:1147-1148.
- Girard M. Hepatitis B universal vaccination: learning from the French experience. *Red Flags*, Aug 10, 2005. Available at: www.redflagsdaily.com/articles/2005_aug10.html. Accessed Dec 1, 2005.
- Anon. Why hepatitis-B vaccine for all? *City Express*, Oct 12, 2005.
- VHPB. Response by the World Health Organization’s GACVS to the paper by MA Hernan et al.: Recombinant hepatitis B vaccine and the risk of multiple sclerosis. *Viral Hepatitis* 2004;13:11.
- Zipp F, Weil JG, Einhaupl KM. No increase in demyelinating diseases after hepatitis B vaccination. *Nat Med* 1999;5:964-965.
- Anon. Good news on hepatitis B vaccination in Europe. *Scrip* 1997;(2288):22.
- Fisher MA, Eklund SA. Hepatitis B vaccine and liver problems in U.S. children less than 6 years old, 1993 and 1994. *Epidemiology* 1999;10:337-339.
- Fisher MA, Eklund SA, James SA, Lin XH. Adverse events associated with hepatitis B vaccine in US children less than six years of age, 1993 and 1994. *Ann Epidemiol* 2001;11:13-21.
- Geier MR, Geier DA. Hepatitis B vaccination safety. *Ann Pharmacother* 2002;36:370-374.
- Hernan M, Jick S, Olek M, Jick H. Recombinant hepatitis B vaccine and the risk of multiple sclerosis.: a prospective study. *Neurology* 2004;63:838-842.
- Geier DA, Geier MR. Hepatitis B vaccination and arthritic adverse reactions: a followup analysis of the Vaccine Adverse Events Reporting System (VAERS) database. *Clin Exp Rheumatol* 2002;20:119.
- Hernan M, Jick S, Olek M, Ascherio A, Jick H. Recombinant hepatitis B vaccine and the risk of multiple sclerosis. *Pharmacoepidemiol Drug Saf* 2003;12:S59-S60.
- DeStefano F, Verstraeten T, Jackson LA, et al. Vaccinations and risk of central nervous system demyelinating diseases in adults. *Arch Neurol* 2003;60:504-509.
- Van Damme P; Kane M. Proceedings of the International Congress. Action towards control of hepatitis B as a community health risk. Cannes, Nov 22-24, 1993. Introduction. *Vaccine* 1995; vol 13(suppl 1):S5.
- Van Damme P, Banatvala J, Fay O, et al. Hepatitis A booster vaccination: is there a need? *Lancet* 2003;362:1065-1071.
- Labbé C, Le Taillanter M, Recacens O, et al. L’habile stratégie d’un labo. *Sciences et Avenir*, January 1997, p 27.
- Bégué P, Denis F, Goudeau A., et al. Vaccination contre l’hépatite B en France. Bilan de la campagne de vaccinations en 1995. *La Revue du Praticien*, May 12, 1997.
- Carnall D. Shire Hall Communications and the case for hepatitis B immunisation. *BMJ* 1996;313:825.
- Beeching NJ. Hepatitis B infections. *BMJ* 2004;329:1059-1060.
- Ress P. International conference “mildly optimistic” about bird flu. *BMJ* 2005;331:1099.
- Briet S. Bernard Vallat de l’OIE critique l’OMS pour sa gestion de la grippe aviaire. *Libération*, Nov 12, 2005.
- Anon. Denmark highlights report on adverse reactions to flu vaccines. *Scrip* 2005;(3101):6.