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[Fast-tracked Swine Flu Vaccine under Fire](#)

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This report has been submitted to Sir Liam Donaldson, Chief Medical Officer of the UK, and to the US Food and Drugs Administration:

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Dear Dr. Joshua Sharfstein, Ms. Christine Walsh, and Professor Sir Liam Donaldson

I write on behalf of the Institute of Science in Society, a not for profit organisation founded in 1999, dedicated to providing reliable and accessible scientific information to the public and to promoting social accountability and sustainability in science.

We are very concerned over the stockpile of experimental vaccines that appear to be intended for mass vaccination. Please allow me to submit the enclosed report, also pasted below, which summarises existing evidence on why mass vaccinations especially of school children should not be undertaken. The vaccines are likely to be ineffective, and the side effects worse than the disease they are supposed to prevent. The vaccines have not been fully tested for safety and the intended adjuvants include ingredients well known to be toxic.

Yours sincerely,

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Please forward widely to your government representatives, wherever you are

Fast-tracked Swine Flu Vaccine under Fire

The vaccines far more deadly than the swine flu; mass vaccinations a recipe for disaster

Dr. Mae-Wan Ho and Prof. Joe Cummins

A swine flu outbreak occurred in Mexico and the United States in April 2009 and spread rapidly around the world by human-to human transmission. The new type A H1N1 influenza virus is unlike any that had been previously isolated [1, 2], judging from the first data released in May. It is a messy combination of sequences from bird, human and swine flu virus lineages from North America and Eurasia. A senior virologist based in Canberra, Australia, told the press he thought that the virus could have been created in the laboratory and released by accident [3]. Some even suggest it was made intentionally as a bioweapon [4], while others blame the intensive livestock industry and extensive trafficking of love animals over long distances, which provide plenty of opportunity for generating exotic recombinants [5]. But what worries the public most is the mass vaccination programmes governments are putting in place to combat the emerging pandemic, which could well be worse than the pandemic itself.

Watchdog opposes fast-track vaccine for school children

The US government is intending to vaccinate all children in September when school re-opens, and the country's vaccine watchdog National Vaccine Information Center (NVIC) has called on the Obama Administration and all state Governors to provide evidence that the move is [6] "necessary and safe", demanding "strong mechanisms for vaccine safety screening, recording, monitoring, reporting and vaccine injury compensation."

The US Departments of Health and Homeland Security had declared a national public health emergency in April soon after the swine flu outbreak. As a result, some schools were closed, people quarantined, and drug companies were given contracts worth \$7billion to make vaccines that are being fast tracked by the Food and Drugs Administration [7]. That means they will only be tested for a few weeks on several hundred children and adult volunteers before being given to all school children this fall.

Furthermore, under federal legislation passed by Congress since 2001, an Emergency Use Authorization allows drug companies, health officials and anyone administering experimental vaccines to Americans during a declared public health emergency to be protected from liability if people get injured. US Secretary of Health and Human Services Kathleen Sebelius has granted vaccine makers total legal immunity from any lawsuits that may result from any new swine flu vaccine. *And some states may make the vaccination mandatory by law.*

The NVIC is asking whether the states are prepared to obey vaccine safety provisions in the 1986 National Childhood Vaccine Injury Act, which include: 1. Giving parents written information about vaccine benefits and risks before children are vaccinated; 2. Keeping a record of which vaccines the children get, including the manufacturer's name and lot number; 3. Recording which vaccines were given in the child's medical record; and 4. Recording serious health problems that develop after vaccination in the child's medical record and immediately making a report to the federal Vaccine Adverse Event Reporting System.

NVIC also wants to know if the states are prepared to provide financial compensation to children injured by the swine flu vaccines, whether parents will be given "complete, truthful information about swine flu vaccine risks", and have the right to say "no" to vaccination.

Co-founder and president of NVIC Barbara Loe Fisher said [6]: "Parents and legislators should be asking themselves right now: Why are children the first to get experimental swine flu vaccines? Are schools equipped to get signed informed consent from parents before vaccination, keep accurate vaccination records and screen out children biologically at high risk for suffering vaccine reactions? Will people giving these vaccines know how to monitor children afterwards and immediately record, report and treat serious health problems that develop? And will states have the financial resources to compensate children who are injured?"

WHO and mass vaccination fever

The mass vaccination order has come from the World Health Organization (WHO) [8]. In early July 2009, a group of vaccination experts concluded that the pandemic is unstoppable, and Marie-Paul Kieny, WHO director on vaccine research said all nations will need access to vaccines, and that a vaccine should be available as early as September.

Critics point out that the 'vaccination experts' are dominated by the vaccine makers standing to gain from the enormously lucrative vaccine and antiviral contracts awarded by governments. But the decisive argument against mass vaccinations is that flu shots simply don't work and are dangerous [9].

Flu shots ineffective and increase risks of asthma

There are widely acknowledged reasons why flu vaccines won't work, as already pointed out with regard to the much touted vaccines against the 'pandemic bird flu' that has yet to materialize [10] ([How to Stop Bird Flu Instead](#), SiS 35). The flu virus changes quickly - even without the help of genetic engineering in the laboratory, and especially with the help of the intensive livestock industry - whereas the vaccines target specific strains. Furthermore, flu vaccination does not give permanent protection, and must be repeated annually; the vaccines are difficult to mass-produce, and some strains won't grow at all under laboratory conditions.

Numerous studies have documented that flu shots give little or no protection against infection and illness, and there is no reason to believe that swine flu vaccines will be different.

A review of 51 separate studies in 2006 concluded that flu vaccines worked no better than a placebo in 260 000 children ranging in age from six months to 23 months [11]. A report published in 2008 found flu vaccines in young children made no difference in the number of flu-related doctor and hospital visits [12].

On the other hand, a study of 800 children with asthma found that those receiving a flu vaccine had a significantly increased risk of asthma-related doctor and emergency room visits [13]; the odds ratios were 3.4 and 1.9 respectively. This was confirmed in a report published in 2009, which showed children with asthma who received FluMist had a 3-fold increased risk of hospitalization [14]

Flu vaccines are equally useless for adults, including the elderly, giving little or no protection against infection or illnesses including pneumonia (see [9]).

Toxic adjuvants in flu vaccines

Vaccines themselves can be dangerous, especially live, attenuated viral vaccines or the new recombinant nucleic acid vaccines [10], they have the potential to generate virulent viruses by recombination and the recombinant nucleic acids could cause autoimmune diseases.

A further major source of toxicity in the case of the flu vaccines are the adjuvants, substances added in order to boost the immunogenicity of the vaccines. There is a large literature on the toxicities of adjuvants. Most flu vaccines contain dangerous levels of mercury in the form of thimerosal, a deadly preservative 50 times more toxic than mercury itself [9]. At high enough doses, it can cause long-term immune, sensory, neurological, motor, and behavioural dysfunctions. Also associated with mercury poisoning are autism, attention deficit disorder, multiple sclerosis, and speech and language deficiencies. The Institute of Medicine has warned that infants, children, and pregnant women should not be injected with thimerosal, yet the majority of flu shots contain 25 micrograms of it.

Another common adjuvant is alum or aluminium hydroxide, which can cause vaccine allergy, anaphylaxis, and macrophage myofascitis, a chronic inflammation syndrome, In cats, alum also gives rise to fibrosarcomas at the site of injection [15]. Numerous new adjuvants are no better, and could be worse. According to a recent review in a science and business pharmaceutical publication [15], most newer adjuvants including MF59, ISCOMS, QS21, AS02, and AS04 have “substantially higher local reactogenicity and systemic toxicity than alum.”

Current status of swine flu vaccines

Five different companies have been contracted to produce vaccines worldwide: Baxter International, GlaxoSmithKline, Novartis and Sanofi-Aventis and AstroZeneca [16]. Already stretched beyond capacity, there is every intention to make smaller vaccine doses go further with a range of new adjuvants [17], with the blessing of the WHO (see later).

Flu vaccines are traditionally produced from non-virulent (attenuated or weakened) influenza viruses (see Box for a description of the viruses). To be effective, the genes of the non- virulent virus used must match those of the viral strain spreading in the population. Activation of the immune system

by exposure to the non pathogenic form of the circulating pathogenic strain leads to the production of antibodies that will confer protection against the pathogenic strain. Producing the non-virulent virus involves first identifying and then recreating the subtypes of two of the virus's surface proteins, haemagglutinin (H) and neuraminidase (N), which determine the strain's virulence and ability to spread, and are also the target proteins for vaccine production.

Influenza viruses

There are 3 types of influenza viruses, A, B and C. The influenza A type virus is the main one that cause diseases in birds and mammals. Its genome consists of 8 segments of RNA coding for 11 proteins, and the viruses are further classified by subtype on the basis of the two main surface glycoproteins (proteins with complex carbohydrate side chains): haemagglutinin (H) and neuraminidase (N) [18]. The segmented genome enables the virus to 'reassort' (shuffle) segments as well as recombine within segments, thereby greatly increasing the rate of evolution and generation of new strains. Reassortment is also widely exploited in the laboratory in the process of creating vaccine strains. To-date, 16 H and 9 N subtypes have been detected in numerous combinations circulating in wild birds [19].

Seed viruses are first made to provide the starting material for large scale production of live non-virulent flu viruses. The seed viruses are approved by the WHO or the United States Food and Drug Administration (USFDA). The usual method of seed virus production is reassortment (see Box). Fertilized chicken eggs are injected with both a standard non-pathogenic influenza strain known to grow well in eggs and the strain that carries the genes expressing the desired vaccine H and N protein subtypes. The two viruses multiply, and their eight genome segments reassort with 256 possible combinations. The resulting recombinant viruses are then screened for the desired virus with the six genome segments that allow the standard strain to grow so well in eggs and the H and N genes from the circulating strain. The seed virus is then injected into millions of eggs for mass production of vaccine. This conventional method of seed stock production takes about one to two months to complete [20].

Cell culture systems may eventually replace chicken eggs. Baxter International applied for a patent on a process using cell culture to produce quantities of infecting virus, which are harvested, inactivated with formaldehyde and ultraviolet light, and then detergent [21]. Baxter has produced H5N1 whole virus vaccines in a Vero cell line derived from the kidney of an African green monkey, and conducted phase 1 and 2 clinical trials with and without aluminium hydroxide as adjuvant [22, 23]. The main finding was that the toxic adjuvant did not increase neutralising antibodies against the vaccine strain. Baxter has agreed to ship H1N1 vaccine by the end of July or early August 2009 but details of the production of that vaccine have not yet been released to the public [16].

In December, a Baxter facility in Austria sent a human flu vaccine contaminated with the deadly H5N1 live avian flu virus to 18 countries, including the Czech Republic, where testing showed it killed the ferrets inoculated [24]. Czech newspapers questioned whether Baxter was involved in a deliberate attempt to start a pandemic.

Novartis, another big pharma, announced on 13 June that it, too, has produced a swine flu vaccine using cell-based technology and the proprietary adjuvant MF59®. The MF59® adjuvant is oil

based and contains Tween80, Span85, and squalene [25]. In studies of oil-based adjuvants in rats, the animals were rendered crippled and paralyzed. Squalene brought on severe arthritis symptoms in rats, and studies in humans given from 10 to 20 ppb (parts per billion) of squalene showed severe immune system impact and development of autoimmune disorders [26].

Novartis was in the news in 2008 for a clinical trial of a H5N1 vaccine in Poland. The trial was administered by local nurses and doctors who gave the vaccine to 350 homeless people, leaving 21 died; and were prosecuted by the Polish police [27, 28]. Novartis claimed the deaths were unrelated to the H5N1 vaccine [29], which had been “tested on 3500 other people without any deaths.”

GlaxoSmithKline’s vaccine will be made up of antigens of the recently isolated influenza strain, and also contains its own proprietary adjuvant system AS03 that has been approved in the EU along with its H5N1 bird flu vaccine in 2008. According to the European Public Assessment Report [30], AS03 adjuvant is composed of squalene (10.68 milligrams), DL-a-tocopherol (11.86 milligrams) and polysorbate 80 (4.85 milligrams). The H5N1 vaccine also contains 5 micrograms thiomersal, as well as Polysorbate 80, Octoxynol 10, and various inorganic salts. The company is aggressively promoting various adjuvant systems as its ‘adjuvant advantage’ that reduces the dose of vaccines [31].

A recent WHO survey of primary vaccine producers concluded that the potential output of 4.9 Billion doses of H1N1 vaccine per year is a best-case scenario, assuming among other factors that the most dose-sparing formulation (that will include toxic adjuvants) be selected by each manufacturer and that production will take place at full capacity. WHO Director-General, Dr .Margaret Chan, and the United Nations Secretary-General, Mr Ban Ki-moon, met with senior officials of vaccine manufacturers on 19 May and asked them to reserve part of their production capacity for poor countries that would otherwise have no or little access to vaccine in the case of a pandemic [32].

The last mass-vaccination in the US was a disaster. In 1976, cases of swine flu were found in soldiers at Fort Dix, New Jersey, and one of them died, most likely of physical overexertion rather than from the infection [7]. This led to the launch of a mass vaccination of 40 million against a pandemic that never materialized. Thousands filed claims for injury. At least 25 died and 500 developed paralyzing Guillain-Barre syndrome [33, 34].

Swine flu syndromes mostly mild

As of 22 July 2009, the CDC listed a total of 40 617 cases in the US, with 319 fatalities, giving a fatalities/case ratio of 0.8 percent [35]; though the real death rate – among all cases of infection including the mild ones that go unreported – is probably much lower. Experts estimate that only 1 out of 20 cases are reported [36].

The UK is the worst affected European country, and the pandemic is in the headlines everyday in July. A new telephone helpline was set up on 23 July to let people get advice and tamiflu without seeing a doctor. In that week, there has been a record rise in cases to 100 000 and a total of 30 deaths so far [37], giving a fatalities/case ratio of 0.03 percent, a more accurate reflection of the actual death rate.

UK's chief medical officer Sir Liam Donaldson has ordered the NHS to plan for as many as 65 000 deaths, with 350 a day at the peak [38]. There has been no plan as yet for mass vaccination; but the UK government has advance orders for 195 million doses of vaccine with GlaxoSmithKline (GSK).

The vaccine that GSK is developing will be tested on a limited number of people as the UK drug company reportedly [39] "weighs the pandemic danger against the risks of an unsafe shot." This was criticized as "risky" by Prof. Hugh Pennington, a retired microbiologist at the University of Aberdeen, Scotland. "By limiting clinical trials, Glaxo raises the danger that the vaccine dose isn't properly calibrated, and could lead to shots that don't protect people from the virus or at worse are unsafe," Pennington said.

Pennington added that the shot's ability to trigger the body's defences is crucial and requires tests to determine the best dose and whether an adjuvant is needed to bolster the immunity. (As we know, GSK is definitely promoting its new range of toxic adjuvants.) He also referred to the Fort Dix incident in 1976 (see earlier).

France has ordered vaccines from Sanofi, GSK and Novartis, but sees no reason to ask vaccine makers to shorten or skip clinical trials [16]. Sanofi-Aventis, the French drug maker developing its own swine flu vaccine will begin testing the product in early August, and estimates it will need as much as two and a half months of tests before having a shot that's "both safe and protective", according to Albert Garcia, speaking for the company's vaccine unit, "the vaccine will be ready in November or December, he said.

Baxter, however, will produce a vaccine by early August for clinical tests.

Glaxo also said it is developing a face mask coated with antivirals to prevent infection and boosting production of its Relenza drug for patients already suffering from swine flu.

There are obviously safer and more effective ways to combat the pandemic than mass vaccinations: washing hands often, sneezing into a tissue that can be safely disposed of, avoiding unnecessary gatherings, and delay opening schools – all advised by governments - and we would add, eating healthily, exercise, and getting enough vitamin D to boost your natural immunity [10].

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