

Citizens petition to recall all vaccines that contain ingredients that have not been shown to be safe

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Abstract

This is a petition to the Commissioner of Food and Drug Administration (FDA) filed under 21 CFR 5, 10 to request a recall of all vaccines that contain ingredients that have not been shown to be safe. The FDA has a responsibility, not fully met, to regulate these products on behalf of the public's health and well-being, but safety is in the hands of those who have been mandated to promote vaccine and are party to lawsuits by vaccine injured children. There has never been any accountability for the SV40 virus given to millions upon millions of Americans in the polio vaccine. This virus is now found in many lymphomas and solid tumors. Nor has there been accountability for any untoward ingredient in vaccine, so contaminated vaccines are used with abandon and there is no understanding of the synergy of toxic ingredients. Regulations of both safety and efficacy should be keeping these poisons from the public but the regulations are not being enforced.

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Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1061,
5630 Fishers Lane, Rockville, MD 20852.

CITIZENS PETITION

Request

The undersigned, K Paul Stoller, MD, submits this petition to the Commissioner of Food and Drugs or Acting Commissioner under 21 CFR 5, 10 to request the Commissioner of Food and Drugs to recall all vaccines that contain ingredients that have not been shown to be safe.

Under the new terrorism law, the U.S. Food and Drug Administration (FDA) has the right to recall dangerous chemicals even without request from the manufacturer.

Rationale

I am making this petition to the FDA because the vaccine policy in the USA has been unduly influenced by vaccine manufacturers and the FDA has a responsibility, not fully met, to regulate these products on behalf of the public's health and well-being.

Every drug that is advertised on TV or radio makes some attempt to reveal possible side effects or complications, but vaccine is promoted on those same airways with nothing said about risks or potential complications.

The clout that pharmaceutical companies have in the world of medicine is both pernicious and all pervasive. They essentially control what "scientific" articles get published in medical journals regarding vaccine [1]. "Conclusion: Publication in prestigious journals is associated with partial or total industry

funding, and this association is not explained by study quality or size."

Even the FDA, which receives a large proportion of its operating budget directly from pharmaceutical companies, has been compromised in this sense.

The HHS, NIH, CDC are no longer in a position ethically, morally and scientifically to conduct research in this arena because they are, to a greater or lesser degree, always party to lawsuits of those who are vaccine-injured or are mandated to promote vaccine. Safety is in the hands of those who have been mandated to promote vaccine—an operational model that has never been demonstrated to work.

There has been no scientific examination of what the increasing number of vaccines and doses of vaccines is doing to children receiving those vaccines. That is an act of omission, but there have been acts of commission as a decade ago the Public Health Service and American Academy of Pediatrics (AAP) called for the removal of Thimerosal (49.55% mercury by weight) in the manufacture of all vaccines which has not taken place (most doses of influenza vaccine approved for children are Thimerosal-preserved).

This is not just about mercury however, as today there are currently eight childhood vaccines that contain aluminum ranging from 125 to 850 micrograms (mcg). These vaccines are administered 17 times in the first 18 months of life, an almost six-fold increase compared to the vaccine schedule of the 1980s. Maximum daily limits to prevent aluminum neurotoxicity have been determined to be no more than 5 mcg per kilogram of body weight per day [2].

The hepatitis B vaccine, administered at birth, contains 250 mcg.

In a 1996 policy statement, "Aluminum Toxicity in Infants and Children," the AAP states, "Aluminum can cause neurological harm. People with kidney disease who build up blood-stream levels of aluminum greater than 100 mcg per liter are at risk of toxicity. The toxic threshold of aluminum in the blood-

stream may be lower than 100 mcg per liter.” Yet, a 2 month old will typically receive 1250 mcg of aluminum from vaccine—that would put the blood level of aluminum 25 times higher than the level that the AAP policy indicates is a risk for toxicity (assuming a 2 month old has about a half liter of blood).

This isn’t just about heavy metals either. There has never been any accountability for the SV40 virus given to millions upon millions of Americans in the polio vaccine. This virus is now found in many lymphomas and solid tumors. This is not just a historical fact, because today the same problem persists, that is, contaminated vaccines are used with abandon.

It is no secret (except to the public) that reverse transcriptase (RT) is present in all chicken cell derived vaccines [3] (Flu vaccine, MMR, Yellow Fever). RT is present because these vaccines are contaminated with avian retrovirus particles and these viruses are associated with leukemia found in wild birds. Not only is there a risk that the measles virus could combine with the cancer causing retrovirus to create a new virus, but that viral DNA could combine with the human genome to cause cancer in its recipients [4]. All egg-based vaccines are contaminated.

There isn’t even valid data that shows that vaccination with the influenza vaccine protects those vaccinated from getting influenza—only data showing some percentage (>65%) of those vaccinated develop "adequate" antibody titers against the three strains in the vaccine that was administered.

In-use studies have shown that flu vaccine to be ineffective in protecting the children vaccinated with them from getting influenza [5,6].

Thimerosal-preserved formulations of the influenza vaccines have not been proven to be “safe” to the minimum standard, “sufficiently nontoxic ...”, required of the manufacturers by a binding federal current good manufacturing practice (CGMP) regulation (21 CFR § 610.15(a)). Clearly, there are regulations of both safety and efficacy that should be keeping these poisons from the public but the regulations are not being enforced.

The binding regulations requiring this proof of safety before a vaccine formulation can be approved by the FDA is set forth in 21 CFR § 601.4(a), and yet the FDA has approved them regardless. Since Thimerosal, for example, has not been proven safe to one of the requisite CGMP safety standard minimums, “sufficiently nontoxic ...”

Thimerosal-preserved vaccines are "deemed to be adulterated" drugs under 21 U.S.C. § 351(a)(2)(B). Thus, Thimerosal-preserved influenza vaccines are “adulterated” drugs that cannot be legally distributed (see 21 U.S.C. § 331(a)).

Conclusion

The approval of vaccine and drugs, the policy and mandates of our public health programs, the research that is funded and eventually published cannot be dictated based on what will make money for a pharmaceutical company. For example, the CDC has promoted flu shots for pregnant women even though the FDA has NEVER approved flu shots for this use. Most doses of the flu shots STILL contain some level of Thimerosal, a known human ABORTAFACTANT, and TERATOGEN.

The FDA must meet their mandated responsibility in this matter and take emergency action to recall all vaccine that contains ingredients that have not been proven to be safe.

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petition which are unfavorable to the petition.

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Date

No environmental impact statement is required by this petition.

References

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- [6] <http://www.cbc.ca/health/story/2006/05/02/flu-shots060502.html> - Flu cases didn’t drop with Ontario’s free shots: study. Last Updated: Tuesday, May 2, 2006 | 4:28 PM ET CBC News “Ontario’s free vaccine program doesn’t appear to have curtailed annual outbreaks of influenza, but some experts are questioning the study’s conclusions and the province’s lack of record keeping. Ontario began paying for flu shots for residents in 2000, at a cost of more than \$50 million a year.”