

# PROPOSED EMPLOYEE INFLUENZA VACCINE PROTECTION ACT

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## INTRODUCTION

Legislation is needed that prohibits businesses and governments from mandating influenza vaccines for employees, or provides penalty-free exemptions to any influenza vaccine mandates on medical, religious and personal/philosophical grounds. Such legislation is compelled by the fact that:

- 1) Multiple mainstream medical sources show that influenza vaccines are of questionable effectiveness or even counterproductive;
- 2) National Vaccine Injury Compensation Program statistics show that influenza vaccines cause more vaccine injuries and deaths than all other vaccines combined; and
- 3) Pharmaceutical companies routinely engage in massive criminal behavior, and are thus ethically unsuitable providers of mandated medical products.

Two examples of protective language:

1. Massachusetts health department regulation 105 CMR 130.325:

(F) Exceptions.

(1) A hospital shall not require an individual to receive an influenza vaccine pursuant to [citations omitted] if:

(a) the vaccine is medically contraindicated, which means that administration of influenza vaccine to that individual would likely be detrimental to the individual's health;

(b) vaccination is against the individual's religious beliefs; or

(c) the individual declines the vaccine.

(2) An individual who declines vaccination for any reason shall sign a statement declining vaccination and certifying that he or she received information about the risks and benefits of influenza vaccine.

2. Maine statute ME Rev. Stat. Tit. 22 Sec. 802 Authority of department:

B. A religious or philosophical exemption is available to an employee who states in writing a sincere religious or philosophical belief that is contrary to the immunization requirement of this subchapter. [2001, c. 185, §2 (NEW).]

The attached pages document the compelling need for employee protection from scientifically unsupported, profit-driven mandatory influenza vaccine policies.

Respectfully Submitted,

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## MEDICAL SUMMARY

- A 2007 *Lancet* study found: “Recent excess mortality studies were unable to confirm a decline in influenza related mortality (flu deaths) since 1980, even as vaccination coverage increased from 15% to 65%.”<sup>i</sup>
- A 2008 *Lancet* study reported that the flu shot did not reduce risk of pneumonia in the elderly.<sup>ii</sup>
- During the 2009-2010 swine flu pandemic, the AMA and the CDC endorsed non-mandatory flu vaccine policies,<sup>iii</sup> suggesting no need for mandates outside of a pandemic.
- A 2010 review of the flu vaccine literature for healthy adults by the Cochrane Collaboration, an independent, international consortium of medical researchers, issued a “WARNING” stating that “reliable evidence on influenza vaccines is thin but there is evidence of widespread manipulation of conclusions...” The review also found that “vaccine use did not affect . . . working days lost” and “had no effect on hospital admissions or complication rates.”<sup>iv</sup>
- A 2010 Cochrane review of all existing literature on the effectiveness of flu vaccine campaigns in the elderly showed that “the available evidence is of poor quality and provides no guidance regarding the safety, efficacy, or effectiveness of influenza vaccines for people aged 65 or older.”<sup>v</sup>
- A 2011 Occupational Safety and Health Administration (OSHA) Position Statement said it “believes there is insufficient scientific evidence for the federal government to promote mandatory influenza vaccination programs that do not have an option for the HCP [healthcare professionals] to decline for medical, religious and/or personal philosophical reasons.”<sup>vi</sup>
- A 2011 *Lancet* study revealed that flu vaccines are 60% effective. However, the 60% figure was the “relative risk reduction” (rounded up); the “actual risk reduction” was a trivial 1.5%.<sup>vii</sup>
- A 2012 *Lancet* study stated: “There are no randomized controlled trials showing efficacy of TIV (the inactive flu virus) in people aged 2-17 years or adults aged 65 and older. For LAIV (the live flu virus), there are no randomized controlled trials showing efficacy in people aged 8-59.”<sup>viii</sup>
- A 2012 critical review in *The International Journal of Family Medicine* concluded: “The arguments for uniform healthcare worker influenza vaccination are not supported by existing literature. The decision whether to get

vaccinated should, except possibly in extreme situations, be that of the individual healthcare worker, without legal, institutional, or peer coercion.”<sup>ix</sup>

- A 2013 BMJ article documented that public health authorities’ aggressive promotion of the influenza vaccine is not supported by the medical literature and fails to acknowledge serious vaccine risks. E.g., contrary to wildly mistaken claims, only 16% of tested respiratory specimens are positive for influenza, and serious vaccine adverse events are well documented internationally.<sup>x</sup>
- In 2013, the Center for Infectious Disease Research and Policy (CIDRAP) at the University of Minnesota reported on studies showing that the influenza vaccine provided “little or no protection” in 2010-11, and that getting a flu shot 2 years in a row may actually lower protection.<sup>xi</sup>
- A 2014 “Systematic Review of Mandatory Influenza Vaccination in Healthcare Personnel” in the *American Journal of Preventive Medicine* concluded that “evidence on clinical outcomes is lacking.”<sup>xii</sup>
- A 2014 *Pediatric Infectious Disease Journal* study found that the trivalent influenza vaccine “was not observed to ameliorate symptoms or viral shedding among vaccine failures (infections occurring among vaccinated persons) compared with infected placebo recipients.”<sup>xiii</sup>
- A 2014 Cochrane Summary found that influenza vaccination “shows no appreciable effect on working days lost or hospitalization.”<sup>xiv</sup>

## LEGAL SUMMARY

### I. INFLUENZA VACCINE INJURY AND DEATH

The National Childhood Vaccine Injury Act of 1986<sup>xv</sup> (NCVIA) created the National Vaccine Injury Compensation Program (NVICP),<sup>xvi</sup> a “vaccine court” system that is a division of the Federal Court of Claims. The NVICP has adjudicated 13,654 vaccine injury and death cases to date (children and adults), with 1904 petitions currently pending as of November 3, 2014. The NVICP has paid out over \$2.8 billion in awards for vaccine injuries and deaths, over \$110 million annually on average,<sup>xvii</sup> and officials from the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA, the agency that

license vaccines for use in the U.S.), and other experts and agencies including the Association of American Physicians and Surgeons (AAPS), have estimated that 90 to 99% of serious vaccine adverse events are never even reported at all,<sup>xviii</sup> despite a federal law requiring doctors to report suspected vaccine adverse events, 42 U.S.C. § 300aa-25.

In 2011, the U.S. Supreme Court ruled that vaccines are “unavoidably unsafe,” *Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068, 179 L.Ed.2d 1 (2011),<sup>xix</sup> which is why the federal government compensates vaccine victims. Vaccine manufacturers were going out of business in the early 1980’s from court awards for vaccine injury and death, so the NCVIA has relieved the vaccine manufacturers from virtually all liability for the harm caused by their products. Vaccine injury and death cases have given rise to a growing area of legal specialization. The Federal Court of Claims lists 129 lawyers in the U.S. that represent vaccine injury and death victims and families.<sup>xx</sup> Individual settlements and awards range from 10’s of thousands to 10’s of millions of dollars. One firm’s website posts settlements and awards in 203 cases over a 4+ year period, including 11 vaccine deaths (5.4%), with individual payouts ranging from \$10,961 to \$61,000,000.<sup>xxi</sup> 84% of these cases were influenza vaccine injuries and deaths; 70% involved Guillaine Barre Syndrome (as of September 23, 2014).

## II. PHARMACEUTICAL INDUSTRY CRIMINAL ACTIVITY

The pharmaceutical industry is the biggest defrauder of the federal government under the False Claims Act.<sup>xxii</sup> In 8 years (2004-2012), there were twenty settlements in the \$345 million to \$3 billion range.<sup>xxiii</sup> Criminal fines in the \$100’s of millions are common, and have topped out at \$1 billion (Pfizer 2009, GlaxoSmithKline 2012). In the last 5 years, \$19.2 billion were returned to

taxpayers from attempts to defraud federal health programs, more than double that of the previous 5 years (as of February 2014).<sup>xxiv</sup> The point is this:

*No one should ever be required to take a product from an industry that routinely engages in massive criminal behavior.*

## CONCLUSION

Because: 1) The medical literature reveals that influenza vaccines are of little effectiveness, and may even be counterproductive; 2) Influenza vaccines cause substantial disability and death, but ultimately of an unknown quantity due to vast underreporting; and 3) Pharmaceutical companies that manufacture vaccines routinely engage in massive criminal behavior:

A. It is apparent that influenza vaccination policy is being driven by something other than the health of targeted vaccine recipients. Therefore, influenza vaccine decision-making must be put in the hands of individual citizens; and

B. It is morally, ethically, medically, scientifically, and legally necessary to protect employees from mandatory influenza vaccines, by enacting legislation that:

- 1) Prohibits employer and government influenza vaccine mandates, or
- 2) Provides for penalty-free refusal of influenza vaccines on the basis of medical grounds (per the patient's physician's recommendation), religious grounds (consistent with federal civil rights law), and personal/philosophical grounds (with no explanation required).

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<sup>i</sup> Simonson, et al (2007). *Lancet Infect Dis* 7: 658-66

<sup>ii</sup> *Lancet*. 2008 Aug 2;372(9636):398-405. doi: 10.1016/S0140-6736(08)61160-5.

<sup>iii</sup> *AMA meeting: No flu shot mandate for doctors; hand sanitizer pushed*, <http://www.ama-assn.org/amednews/2009/11/23/prsd1123.htm>; Vaccine News and Commentary from the University

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of Pennsylvania Centers for Bioethics, <http://blog.vaccineethics.org/2010/06/cdc-declines-to-endorse-mandatory-flu.html>, citing 75 Fed. Reg. 35497 (June 10, 2010).

<sup>iv</sup> Vaccines for preventing influenza in healthy adults, <http://www2.cochrane.org/reviews/en/ab001269.html>.

<sup>v</sup> Jefferson, T. et al (2010). Cochrane Database of Systematic Reviews. 8: Article #CDOO4879

<sup>vi</sup> National Vaccine Advisory Committee Meeting Minutes, September 13-14, 2011, APPENDIX B: OSHA Position Statement, as submitted by Mr. Borwegen, representative of the Service Employees International Union, <http://www.nvic.org/CMSPages/GetFile.aspx?nodeid=da4b451c-b83e-4eb4-9b64-5c210aad1ec3>

<sup>vii</sup> Flu Shots, Fosamax and Pharmaceutical Fakery: The Common Use of Misleading Statistics in the Medical Literature, Gary G. Kohls, M.D., Dec. 3, 2011, <http://www.thepeoplesvoice.org/TPV3/Voices.php/2011/12/03/flu-shots-fosamax-and-pharmaceutical-fak?tempskin=basic>.

<sup>viii</sup> Osterholm, M. et al (2012). Lancet Infect Dis 12: 36-44

<sup>ix</sup> *What, in Fact, Is the Evidence That Vaccinating Healthcare Workers against Seasonal Influenza Protects Their Patients? A Critical Review*, Int J Family Med. 2012; 2012: 205464, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3502850/>

<sup>x</sup> *BMJ* 2013;346:f3037, [http://www.beyondconformity.org.nz/literature\\_120194/Influenza\\_Doshi\\_13](http://www.beyondconformity.org.nz/literature_120194/Influenza_Doshi_13), May 16, 2013

<sup>xi</sup> Study: Getting flu shot 2 years in a row may lower protection, CIDRAP, March 1, 2013, <http://www.cidrap.umn.edu/cidrap/content/influenza/general/news/mar0113vestudy.html>

<sup>xii</sup> <http://www.ajpmonline.org/article/S0749-3797%2814%2900255-4/abstract>

<sup>xiii</sup> *Pediatr Infect Dis J*. 2014 Feb;33(2):e63-6. doi: 10.1097/INF, <http://www.ncbi.nlm.nih.gov/pubmed/24061274>

<sup>xiv</sup> Demicheli V, Jefferson T, Al-Ansary LA, Ferroni E, Rivetti A, Di Pietrantonj C. Vaccines for preventing influenza in healthy adults. Cochrane Database of Systematic Reviews 2014, Issue 3. Art. No.: CD001269. DOI: 10.1002/14651858.CD001269.pub5 - See more at: [http://summaries.cochrane.org/CD001269/ARI\\_vaccines-to-prevent-influenza-in-healthy-adults#sthash.0BJX2MSk.dpuf](http://summaries.cochrane.org/CD001269/ARI_vaccines-to-prevent-influenza-in-healthy-adults#sthash.0BJX2MSk.dpuf)

<sup>xv</sup> See., e.g., the summary here: <https://www.dshs.state.tx.us/immunize/forms/11-11246.pdf>

<sup>xvi</sup> <http://www.hrsa.gov/vaccinecompensation/index.html>

<sup>xvii</sup> <http://www.hrsa.gov/vaccinecompensation/data.html>

<sup>xviii</sup> The FDA estimates that as few as 1% of serious adverse reactions to vaccines are reported.[a,b] The CDC admits that only about 10% are reported.[c] Congressional testimony revealed that medical students are told not to report suspected adverse events,[d] despite a law requiring doctors to report suspected vaccine adverse events.[e]

[a] Less than 1%, according to Barbara Fisher, citing former FDA Commissioner David Kessler, 1993, JAMA, in the Statement of the National Vaccine Information Center (NVIC), Hearing of the House Subcommittee on Criminal Justice, Drug Policy and Human Resources, "Compensating Vaccine Injuries: Are Reforms Needed?" September 28, 1999.

[b] Less than 10%, according to KM Severyn, R.Ph., Ph.D. in the Dayton Daily News, May 28, 1993.

[c] Fact Sheet on Mandatory Vaccines, American Association of Physicians and Surgeons, <http://www.aapsonline.org/>.

[d] "Mandating Vaccines: Government Practicing Medicine Without a License?" Jane Orient, M.D., Director of the American Association of Physicians and Surgeons, 1999.

[e] 42 U.S.C. § 300aa-25. Recoding and Reporting Information, National Vaccine Injury Compensation Program. <sup>xix</sup> <http://www.supremecourt.gov/opinions/10pdf/09-152.pdf>

<sup>xx</sup> U.S. Court of Federal Claims, Vaccine Attorneys – Complete list, <http://www.uscfc.uscourts.gov/sites/default/files/Vaccine%20Attorneys.pdf>

<sup>xxi</sup> Maglio, Christopher & Toale, Our Firm's Vaccine Case Results, <http://www.mctlawyers.com/vaccine-injury/cases/>

<sup>xxii</sup> "Public Citizen Study: Pharmaceutical Industry Is Biggest Defrauder of the Federal Government Under the False Claims Act," Dec. 20, 2010, <http://www.pharmpro.com/news/2010/12/public-citizen-study-pharmaceutical-industry-biggest-defrauder-federal-government-under-false-claims-act>

<sup>xxiii</sup> List of largest pharmaceutical settlements (2004 – 2012), Wikipedia, [http://en.wikipedia.org/wiki/List\\_of\\_largest\\_pharmaceutical\\_settlements](http://en.wikipedia.org/wiki/List_of_largest_pharmaceutical_settlements)

<sup>xxiv</sup> False Claims Act Whistleblowing Blog, February 2014 archive, <http://www.fraudwhistleblowersblog.com/2014/02/>