IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Gary Null, PhD,
2307 Broadway
New York, New York 10024

Rima E. Laibow, MD,
c/o 58 Plotts Road
Newton, New Jersey 07860

Susanne Field, RN,
233 Red Oak Road
Poughkeepsie, New York 12603

Cherryl Robbins, CNA,
2484 Route 9G, Apt B,
Staatsburg, New York 12580

Mary Kuchman,
87 Galway Drive
Rochester, New York 14623

Heather Walker,
1042 Baker Avenue
Schenectady, New York 12309

Natural Solutions Foundation
c/o 58 Plotts Road
Newton, New York 07860,

and

Foundation for Health Choice
777- K Schwab Rd
Hatfield, Pennsylvania 19440,
Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION,

Civil Action No. _____

COMPLAINT

For Declaratory
And Injunctive Relief

5600 Fishers Lane)
Rockville, MD 20857)
)
and)
)
U.S. DEPARTMENT OF HEALTH AND)
HUMAN SERVICES,)
200 Independence Avenue, S.W.)
Washington, DC 20201)
)
and)
)
KATHLEEN SEBELIUS,)
in her official capacity as Secretary of)
Health and Human Services,)
U.S. Department of Health and Human)
Services)
200 Independence Avenue, S.W.)
Washington, DC 20201)
)
and)
)
MARGARET HAMBURG, M.D., *in her*)
official capacity as Commissioner of Food)
and Drugs,)
U.S. Food and Drug Administration)
10903 New Hampshire Avenue)
Silver Spring, MD 20993)
)
Defendants.)

COMPLAINT
FOR DECLARATORY AND INJUNCTIVE RELIEF

I. Statement of the Case

1. The Complaint in this matter involves the September 15, 2009 Food and Drug Administration (herein, FDA or Agency) approval or licensing of the "Swine Flu" 2009-H1N1-A vaccines (herein, the Vaccines) under Title 21 of the United States Code.[1]

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[1] http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093830.htm

Plaintiffs seek a declaration that the Vaccine approvals or licenses are void, with injunctive relief.

II. Procedural History

2. This matter comes before the Court by way of a Complaint for declaratory judgment and injunctive relief arising from vaccine approval actions (or omissions) of a Federal Agency, the Food and Drug Administration, a primary Executive Department, the Department of Health and Human Services and certain Federal Officials, the Defendants and their subordinates, which they have taken pursuant to 21 U.S.C.A. 355. Plaintiffs are seeking a stay of the Agency's approval of the licensing of the Vaccines and a reversal of the approvals of the licensing. The Plaintiffs seek a Temporary Restraining Order and Preliminary Injunction staying the approvals of the licensing and/or staying any use of the Vaccines, including use under an Emergency Use Authorization (EUA), until there has been adequate safety testing and a full opportunity for public hearings.

3. This is an emergency legal action in a matter of significant public importance. The Agency has approved or licensed the Vaccines without definitive prerequisite safety testing, in clear violation of Federal Law which requires that all drugs (including the Vaccines) be proven "safe and effective" according to all of the applicable established safety and effectiveness standards; and, for said drugs, that the benefits outweigh the risks. Without safety testing, there can be no valid finding that the benefits outweigh the risks or that the Vaccines are "safe and effective." In addition, the Secretary of Health and Human Services (herein, the Secretary), through subordinate officials and agencies, has also moved to authorize the use of unapproved Vaccines through a PREP Act listing

of said Vaccines as pandemic disease items for a novel A/H1N1 influenza virus that has not been found to be either highly contagious or inordinately life threatening.

4. The Plaintiffs are citizens of the United States who are in imminent peril of adverse consequences, credentialed health care professionals and citizen groups engaged in expressive association, health care civil rights activities concerning the approval of the Vaccines. The particular circumstances that lead the individual Plaintiffs to seek redress in this Court are set forth more fully in their Certifications submitted in support of the Motion for Preliminary Injunction, which are included herein by reference as though fully set forth.

(a) Gary Null PhD is a New York licensed (New York State License #111813) dietitian, nutritionist and healthcare worker who is required to receive the Vaccines if he is to be allowed to see his clients in any New York hospital.

(b) Rima E. Laibow MD is a New York licensed (New York State License # 111813) physician who is required to receive the Vaccines if she is to be allowed to see her patients in any New York hospital.

(c) Suzanne Field RN is a New York registered nurse (#480982-1) who had a documented reaction to an influenza vaccination in 2007 and who will not be granted an exemption from receiving the Vaccines in order to keep her job at Vassar Brothers Medical Center, Poughkeepsie, New York.

(d) Cherryl Robbins CNA is a Certified Nursing Assistant (#342679910508R) working at St Francis Hospital, Poughkeepsie, New York as a patient care technician who is 22 weeks pregnant and who will not be granted an exemption from receiving the Vaccines although it is not

recommended that children under one year of age receive the Vaccines; she will lose her job unless she subjects her unborn child to the Vaccines.

(e) Mary Kuchman is a Billing Specialist at Highland Hospital in Rochester, New York without patient contact; she is required to receive the Vaccines or she will lose her job.

(f) Heather Walker is a student at Maria College, New York, matriculated for the Certified Occupational Therapy Assistant course, Student No. 660091650; she has strong conscientious and religious objections to being vaccinated with the Vaccines and will not be able to continue her classes unless she receives the required Vaccines; she stands to lose $2,000 in tuition payments.

IV. Jurisdiction

5. (A) This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 (federal question) and 28 U.S.C. § 1361 (mandamus). The relief requested is authorized pursuant to 28 U.S.C. § 1651 (all writs act); 28 U.S.C. § 2201 (declaratory relief); and 28 U.S.C. § 2202 (further relief). Plaintiffs have a right to bring this action pursuant to the Administrative Procedures Act because the Defendants, including the Agency, have engaged in final agency actions presenting actual controversies for which these Plaintiffs are entitled to relief. Venue is proper in this district pursuant to 28 U.S.C. § 1391(e) because this is a civil action in which at least one of the Defendants is an officer of the United States that resides in this judicial district or an agency of the United States that resides in this judicial district.

(B) Defendant FDA approved four (4) A/H1N1 Vaccines on September 15, 2009 (with planned availability to the public on or about the first week of October 2009) without adequately considering the risks and benefits of the Vaccines. In addition,

Defendant Secretary has listed these vaccines as covered items under the PREP Act because of a " possible health emergency (possible pandemic influenza)" permitting Defendant FDA to issue an "Emergency Use Authorization" (EUA) order under which unapproved vaccines may not only be administered in a mass vaccination program but also uncontrolled vaccine manufacture may be conducted in a manner that fails to provide any assurance that these on-site admixed Vaccines will be safe to administer at the locations (90,000 sites) at which these unapproved vaccines may be manufactured, mixed, prepared and administered.

(C) Upon information and belief, most if not all of the inactivated-influenza Vaccines will be or become unapproved vaccines when the adjuvants, lacking proof of safety to the standard required in 21 CFR Sec. 610.15(a), will be admixed with the "approved" Vaccines at the 90,000 sites outside of all semblance of manufacture under current good manufacturing practice (CGMP) and, thereby, be not only adulterated drugs under 21 U.S.C. Sec. 351(a)(2)(B) but also unapproved drugs, with no assurance of safety, uniformity, or absence of contamination.

V. Ripeness

6. (A) With the approval of the licensing of the Vaccines on September 15, 2009, the controversy over their approval as a "change of strain" vaccine without safety testing, rather than as a "novel virus" vaccine requiring safety testing, became ripe for judicial review. Since one of the Vaccines approved (and the first one that the government is making available to the public) is a "live virus" nasal mist vaccine, made with a virus declared by both the government and the World Health Organization, (W.H.O.) to be a

"novel virus" with pandemic potential, this particular Vaccine poses an immediate risk of irreparable harm.

(B) The determination by the Agency to proceed with licensing the Vaccines as a "change of strain," in light of the Agency's inconsistent prior determination that the 2009-H1N1-A virus is a "novel" virus with pandemic potential, is arbitrary and capricious and is neither supported by the scientific evidence nor transparent. With the threat that the Vaccines will be available to the public on or before October 15, 2009 and several States now mandating their use, the matter is of immediate public concern.

(C) Furthermore, certain Vaccines for which the Secretary has issued a PREP Act "covered item" designation, permitting not only their use but also their manufacture outside of the CGMP minimums that ensure some standard of safety, will therefore be provided to the public without assurance of safety under a declaration that purports to absolve the Defendants from liability therefore. This is the case because, if not stayed, the Secretary's order ("health emergency/possible pandemic outbreak") will permit the federal government to administer all of these Vaccines including those with the "oil and water" adjuvant, not approved for human use.

7. For example, based upon Federal government "recommendations", the State of New Jersey has mandated flu vaccines for all school children; and the State of New York has mandated flu vaccines for all health care workers with patient contact, including the Vaccines subject to the Petition for Review.

VI. Standing

8. The Plaintiffs are all nongovernmental organizations and individual United States citizens who are members of the organizations and the general public. The specific harms which the individual Plaintiffs will suffer as a result of the Agency actions complained of herein are set forth in the aforesaid Certifications of the Plaintiffs which are included herein as though fully set forth.

9. (A) The State of New York has mandated that all healthcare workers with patient contact (with few exceptions) must receive all influenza vaccinations existing at the time the regulation was promulgated, August 13, 2009, as an amendment to Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, Part 66, by adding Subpart 66-3 *Health Care Facility Personnel – Influenza Vaccination Requirements*. The relevant portions of the new regulation, applicable to all influenza vaccinations, including the Vaccines at issue in this Petition state:

> "…all persons… affiliated with a health care facility… including… medical staff… who either have direct contact with patients or whose activities are such that if they were infected with influenza, they could potentially expose patients, or others who have direct contact with patients, to influenza…"
> "…require that the personnel be immunized against influenza virus(es) as a precondition to employment and on an annual basis. Such influenza vaccination(s) must be in accordance with the national recommendations in effect at the time of the vaccination(s)…"

(B) The regulation therefore provides that any future influenza vaccines recommended by the Centers for Disease Control ("national recommendations"), a subunit of Defendant Secretary, shall be included in the regulatory mandate, as a condition of maintaining employment. The licensing of the Vaccines by the Agency is the necessary prerequisite for the recommending by the sub-unit of the Agency and for the automatic mandating of the Vaccines for the covered healthcare workers.

(C) Furthermore, under a "pandemic health emergency," the Defendant Secretary could authorize (and may have already authorized) the use of unapproved vaccines. The Vaccines to which the adjuvant will be added "on site" are clearly unapproveable vaccines. This is the case because Defendant FDA cannot "approve" such Vaccines because they will not be manufactured in an FDA-approved facility but rather at 90,000 locations.

10. (A) The New York regulations violate the 14th Amendment to the United States Constitution in that the regulation deprives the plaintiffs of their Liberty or Property without Due Process of Law and denies them the equal protection of the law, including law protecting exemptions from mandated vaccines based upon religious conscience. The issuing of the approvals or licenses by the Agency and/or, for unapproved Vaccines, and/or a Defendant-issued EUA covering said unapproved Vaccines are necessary prerequisite(s) for the deprivation of rights and interests complained of herein.

(B) Since Defendants have announced the plan to permit "mixing" of the "approved" inactivated-influenza Vaccines with unspecified adjuvant at 90,000 sites, the approval or issuance of the licenses by the FDA is a deprivation of rights of the Plaintiffs; the Secretary's issuance of a "pandemic health emergency" EUA notice purports to permit unapproved and/or unapproveable vaccines to be administered in a mass vaccination campaign. This appears to be the basis for the approvals or licensing, as the necessary prerequisite for the deprivation of rights or interests through the merely

ministerial act of state-level mandating of the Vaccines, the State having, *ultra vires*, abrogated its police power to the discretion of "national recommendations."

(C) Plaintiffs therefore have standing to challenge these authorizations, approvals or licenses as well as the use of an EUA to permit unapproved Vaccines to be administered.

11. These individuals stand in imminent peril of risk of health or life, loss of liberty, property, livelihood or licensure, or public benefits such as public school attendance, as set forth in greater detail in the aforesaid Certifications submitted with the Motion for Preliminary Injunction. Based upon the FDA approvals of the Vaccines and Defendant FDA's issuance of an EUA and/or right to issue an EUA for the unapproved adjuvanted Vaccines, these Plaintiffs are in imminent peril of being coerced, mandated or required to receive the Vaccines against their will and without their fully informed, voluntary consent.

VII Additional Allegations

12. Without taking into account serious objections raised by many United States citizens, the Defendants approved four "Swine Flu" 2009-H1N1-A Vaccines on September 15, 2009. Defendant Secretary of Health and Human Services testified before Congress on that date, announcing the approvals and a program to widely distribute the Vaccines which were purchased by the federal government. The administrative record appears to be defective in that the record as posted on the Defendant Agency web site does not include, for all the approved Vaccines, a drug package insert or label with an

accurate list of ingredients.[2] The Defendant Department or Agency owns all of the Vaccines and possible adjuvants complained of herein.

13. The Food, Drug and Cosmetics Act (FD&C Act) Mission Statement requires that "…'(B) human and veterinary drugs are safe and effective…' (21 USC §393(b)(2)). The Act has been amended repeatedly, to require that no drug be approved unless it is proven 'safe and effective'."

14. The applicable Statutes and Regulations, including but not limited to 21 U.S.C.A. 321, 331, 351(a)(2)(B), 355, 360bbb-3, 393(b)(2), and 21 C.F.R. Part 210, 210.2, Part 211, 211.1, Part 601, 601.2(a), 601.4(a) and 610.15(a) establish a comprehensive regulatory system for the approval (of the licenses for) of the Vaccines, that is binding upon both the federal government and the vaccine companies.

15. The Defendants have arbitrarily and capriciously failed to follow the statutes and regulations, thereby issuing invalid approvals for the Vaccines. The Defendants have failed to obtain from the purported licensees all of the applicable proofs of safety and efficacy to the Agency in the manufacturer's Biologic License Application (BLA) (21 CFR § 601.2(a)) before the Agency can legally approve a vaccine (21 CFR § 601.4(a))

16. If the H1N1 "Swine Flu" vaccination results are similar to the 1976 "Swine Flu" vaccination panic, hundreds, if not thousands, may die (more than are alleged to have died from the 2009 "Swine Flu") and hundreds of thousands or more may be injured. If the Vaccines, with their MF59 proprietary version of squalene and other toxic adjuvants, are as deadly as, if not more deadly than, the experimental squalene Anthrax Vaccine ("Vaccine A") mandated for United States soldiers during the First Gulf War,

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[2] http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093830.htm

hundreds of thousands will be hospitalized due to vaccine adverse reactions with tragic consequences to them and enormous preventable financial burdens on the healthcare system. The purported adjuvant-added formulation of the Novartis vaccine approved by the Agency has a concentration of squalene one million times greater than that present in the experimental squalene-containing Anthrax Vaccine. Squalene has never been approved for use in any drug in the United States. Moreover, the interim use of Vaccine A was permitted under the Order issued by Judge Emmet G. Sullivan in the case of *Doe v Rumsfeld* (Civil Action No. 03-707 in this Court, only on a "voluntary" basis and then with fully informed consent on the part of the recipients. Judge Sullivan's findings of fact, including that squalene is an unapproved drug, were not appealed by the government and the government is therefore bound by that decision.

17. The Agency has, through its public pronouncements and the approvals granted on September 15, 2009, determined that the Vaccines will not be treated as "new drugs" requiring safety testing, but rather as "change of strain" drugs not requiring full, or even prior-to-use, safety testing. This is true although all of the authorities in government and independent organizations, indeed the Agency itself, refer to the A/H1N1 virus that is the basis virus for the Vaccines as a "novel" virus and the manufacture of this vaccine is covered by patents by Baxter International, Novartis and others obtained in 2007 and 2008. The public record shows:

(a) "Norman Baylor, PhD, director of FDA's Office of Vaccines Research and Review, explained the FDA's probable decision to go ahead with the simplified approval process, rather than a lengthy new drug application process. "We have decades of experience with

H1N1, that's why we feel we can do this with a strain-change," said Dr. Baylor."[3] The last time there was a "Swine Flu" vaccine, in 1976[4], the only time in the "decades" alleged by Dr. Baylor for which there was a "Swine Flu" vaccine, the vaccine killed hundreds and maimed thousands in a well-known historical fiasco that forced the Agency to abandon the use of the vaccine after ten weeks of availability to the public. How can the Agency therefore now claim such scientifically valid fore-knowledge of safety for the Vaccines at issue here that safety testing should not be required? Defendants' online "FAQs" page shows:

(b) "Q. Will vaccine be adjuvanted?
A. It is unlikely H1N1 vaccine will be adjuvanted. Definitive information will be available once clinical trial data are available.
Q. If vaccine is adjuvanted, how will it be formulated?
A. Formulation will vary by provider."

Upon information and belief, for Novartis, the vaccine may be preformulated with adjuvant. For CSL, GSK and Sanofi Pasteur, mixing of vaccine and adjuvant at the site of administration will be necessary. Specific information on storage requirements and procedures for mixing vaccine and adjuvant will be provided by CDC. These "adjuvanted" vaccines will be unapproved and unapprovable vaccines since they will be manufactured outside of CGMP in an unregulated (by the FDA) manner using instructions issued by the CDC, a subordinate of the Secretary under a Secretary-issued EUA. The Medimmune vaccine will not be adjuvanted as it is a "live virus" vaccine that is intended to cause a reaction that cannot be distinguished from an influenza infection.

"Q. Will the vaccine be administered under EUA (Emergency Use Authorization)?

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3 http://www.medpagetoday.com/ProductAlert/DevicesandVaccines/15230

4 http://www.cdc.gov/ncidod/eid/vol12no01/05-1007.htm

A. EUA will not be used for unadjuvanted vaccine if FDA licenses the vaccine under the current BLA (Biologics License Application) as a strain change." But EUA will be used for the adjuvanted Vaccines using CSL, GSK (currently unapproved) and Sanofi Pasteur unadjuvanted vaccines as the basis vaccines, because, after mixing they will be unapprovable drugs.[5]

(c) "There's a chance the early data will show the vaccine is ineffective at stimulating an immune response. If that's the case, the FDA might have to issue an "emergency use authorization" for an oil-in-water adjuvant that sparks a stronger reaction in the immune system, but causes more side effects."[6]

18. Two companies, GlaxoSmithKline and Novartis, have applied for approval for vaccines that contain oil and water adjuvants. The NIH is also conducting a dose response trial of an adjuvant-enhanced vaccine and has announced that early results suggest that a single dose of adjuvanted vaccine may be "sufficient." The Agency has purchased nearly a half billion dollars worth of injectable squalene adjuvants.[7]

"There are currently no licensed influenza vaccines that contain an adjuvant, and Dr. Baylor said he couldn't recall a time when the FDA issued an emergency use authorization for a vaccine.[8] …
The panel's consumer representative said if the FDA does issue an emergency use authorization for an adjuvanted vaccine, she would prefer as little adjuvant as possible to avoid side effects...
What do these numbers mean? Protection of humans against seasonal influenza is generally believed to require a HI titer of 1:40 or more. Therefore when MF59 adjuvant is used in mice, one immunization is sufficient to confer protection against disease. Without adjuvant, two doses are required for protection… Trials are ongoing in adults to determine the immunogenicity of 2009 H1N1 vaccines with and without adjuvant."[9]

19. (A) The Agency acknowledges the danger of side effects from this untested, unapproved adjuvant, yet the Secretary, through a listing of these as PREP Act items,

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5 http://www.cdc.gov/h1n1flu/vaccination/statelocal/qa.htm

6 http://www.medpagetoday.com/ProductAlert/DevicesandVaccines/15230

7 http://www.hhs.gov/news/press/2009pres/07/20090713b.html

8 Note: Dr. Baylor apparently forgot the 2005 EUA for Vaccine A which caused Judge Emmett to revise his now apparently moot Permanent Injunction in 2005.

9 http://www.virology.ws/2009/09/01/adjuvant-effect-on-h1n1-vaccine/
https://www.medicalcountermeasures.gov/BARDA/MCM/panflu/factsheet.aspx

now allows the Defendant FDA to issue an EUA, has moved to approve it for use in light of an alleged pandemic from a virus which has so far shown itself to be a not significant threat.

(B) Even if the A/H1N1 virus did pose such a threat, and for which, according to Defendant Secretary Sibelius' aforesaid testimony before Congress, no evidence of a significant mutation toward increased disease-causing capacity exists. Even if A/H1N1 did pose such a threat, the known dangers of squalene adjuvants, used in laboratories as "Freund's Adjuvant" to cause massive auto immune disease, paralyze and create disorders in animals, appears unjustified to the Plaintiffs, and Plaintiff Dr. Rima E. Laibow, MD states so in her Certification in support of this Complaint.

(C) Thus, neither the Secretary nor the Agency has substantiated the need to use such a draconian and dangerous immunological agent.

(D) Upon information and belief some or all of the Vaccine manufacturers are using a novel method of production by culturing the vaccine in a monkey renal cell line. This same cell line was documented by Maurice Hilleman, PhD, Chief Scientist of Merck's Vaccine Division, to be heavily contaminated with SMV40, a leukemia-causing cancer virus. There is no information suggesting that this same contamination does not exist today in the same cell line, thereby suggesting a serious, undisclosed, risk of leukemia in those injected with the novel vaccine.

20. According to the Certification of Plaintiffs' immunologist expert, Dr. Sarah Schon, it is not proper science to treat a "novel" virus vaccine which is produced by a method not heretofore used to produce flu vaccines as a mere "change of strain".

Therefore the Vaccines herein should have been subjected to full safety testing as unapproved new drugs. This reasonable, professional opinion conforms to basic legal and medical ethics principles while any contrary opinion produced by Defendants will be unreasonable and violate both the letter and the spirit of the applicable law.

21. The Agency failed to follow its own regulations with regard to the approval of the Vaccines, including specifically: a) Section 351(a)(2)(B) that the manufacturer must "assure that such drug meets the requirements of this chapter as to safety…", b) the provisions of 21 CFR § 601.2(a),(2)a that require the manufacturer to provide a Certificate of Compliance that all requirements have been met, and c) the provisions of 42 U.S.C.A. §300aa-27(a)(2) that mandate that the Defendant Secretary assure "safer" vaccines by reducing the risks of adverse reactions to said vaccines.

22. (A) When announcing the approval of the licenses of those Vaccines approved by Defendant FDA, Defendant Secretary Sebelius testified before Congress that all the Vaccines would be owned by the government and distributed through a single contract distributor to approximately 90,000 locations, including schools, hospitals and other places of public accommodation. If the "live virus" nasal mist Vaccine, which the manufacturer publicly admits will cause a case of the flu and of which the federal government has already ordered 40 million doses, is released to the public, this act will trigger the very pandemic the federal government claims it wishes to avoid. Further, Defendants have indicated that if an adjuvanted vaccine is used, the vaccine and adjuvant will, for the approved inactivated-influenza Vaccines produced by "CSL, GSK and Sanofi Pasteur", be "mixed" at the sites of the inoculations.

(B) Thus, upon information and belief, an unapproved squalene-laced adjuvant and an unadjuvanted Vaccine will be admixed in uncontrolled, non-sterile circumstances, across the entire country, to make unapprovable Vaccines that will be given under an EUA issued by the Agency, leading to further injuries and ensuring the deadly results of a pandemic induced by the arbitrary and capricious decisions of the Defendants, decisions that are outside of the laws governing drug manufacture and not based on science or testing, or a documented national health emergency.

VIII Requests for Relief

23. Wherefore the Plaintiffs herein petition this Honorable Court for an immediate opportunity to be heard on an application for a Preliminary Injunction, binding upon the Defendants, and all subordinate agents and agencies thereof, temporarily restraining the Commissioner et al., until further Order of the Court, staying the approvals issued under 21 USC 321, under 21 U.S.C.A. § 360bbb-3 (Emergency Use Authorization) or otherwise for any "Swine Flu" 2009-H1N1-A Vaccine, as more fully set forth in the form of Order to Show Cause with Restraints attached hereto; a declaration that the approvals heretofore issued are void; and

an order overturning any current EUA and forbidding the Defendants from issuing another EUA for these Vaccines so as to prevent the use of unapproved drugs (vaccines) such as those that would result when adjuvanted vaccines were used or unapprovable drugs when the adjuvant is permitted to be added to and mixed with the inactivated-influenza Vaccines at the "90,000 sites" around the country using directions issued by the

CDC, an agency that reports to the Defendant Secretary, and for other and further relief to which the Plaintiffs may be entitled.

24. The Plaintiffs seek Judgment including: (1) the reversal of the approvals including any "strain changes" which fall under the manufacturer's existing Biological Licensing Application (BLA) which may not be new licenses, but rather approvals to modify the existing licenses, and (2) immediate injunctive relief covering the following areas:

a. That the Agency reveal the full and complete contents of the Vaccines, the role, presence and dosage/concentration of any adjuvants, including, but not limited to such as squalene and aluminum, the role, dosage/concentration of any alleged "preservatives," such as mercury, all minor, adventitious, residue, preparation remnants, accidental and minor components and the full and complete details of any clinical trials, whether for dosage, immunogenicity, clinical response or any other purpose; and

b. An injunction staying the approvals of any FDA-approved A/H1N1 vaccine until all of the applicable safety testing requirements for new drugs that are also vaccines, including those for preservative safety for the Thimerosal-preserved vaccines are satisfactorily completed and a clear determination can be made that there are significant disease risks which do outweigh the alleged benefits of the various vaccine preparations;

c. An injunction staying the issuance of an EUA referencing these inactivated-"novel A/H1N1"-influenza vaccines and forbidding the Agency from issuing any further EUA for these Vaccines that permits the mixing of an adjuvant with a Vaccine outside of the Vaccine manufacturer's CGMP-compliant facilities; and

d. An order that the approvals of these Vaccines are contingent upon clear restrictions mandating written informed consent and voluntary use, without coercion or risk of loss of liberty, right to health care choice, property, schooling, livelihood, licensure or other public good by any governmental entity so that the citizens' 14th-amendment rights shall be preserved.

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