INTRO

I am a father of 3 young boys, 9, 7 and 2. I have a personal religious objection to mandatory vaccinations because many of the required vaccines were cultured in human cells that emanated from the lungs of an aborted fetus. These "Human Diploid Fibroblasts" are listed by the CDC as being included in many vaccines and I have included that in my submission. You can google "WI-38" and learn all about it for yourselves.

I know the Pope has come out to tell Catholics that it's ok to vaccinate – but forgive me if I don't take my religious cues from a guy who has spent his career shuffling around pedophiles from church to church.

My wife, on the other hand, prefers to go along with whatever the government tells her to do. As a compromise, I have filed Religious Exemptions for our boys; and they receive some, but not all of the recommended vaccines; and the doses are SPACED OUT further in time than is recommended by the CDC. They have both received the MMR vaccine, for instance. (And, of course, we did not allow our newborn babies, with little immunity of their own, to be injected with a vaccine for HEP B as recommended by the CDC, because that disease can only feasibly be attained by way of either SEX or IV Drug Use.

A "Solution" to a Non-Existent Problem

This is NOT a problem in CT.

The danger of Measles is being utterly overblown. If you just landed here from another planet, you might think MEASLES is a new PLAGUE-like virus killing by the dozens. It's MEASLES. The Brady Bunch – the most wholesome family show in TV history – did a whole episode on the Measles and how relatively innocuous it is... and how good it is for kids to develop LIFETIME NATURAL immunity once they've gotten them.

The RELIGIOUS EXEMPTION has been a part of the State's Vaccine Mandate since it was first enacted in 1959 and it has NEVER been a problem. And it is NOT a problem now!

The statistics that came out last week show that CT is among the states with the HIGHEST overall Vaccination Rate (96.5% - and 98% for Kindergartners and 7th Graders) in the country and we have had a mere 3 cases of measles this year – and ALL IN ADULTS.

There are some 700 measles cases nationwide – that averages out to 14 per State – and most of those are in pockets of UNVACCINATED people, like the Ultra-Orthodox Jews across the Tappan Zee in Rockland County.

So, there isn't ANY danger or threat in CT that would warrant removing exemptions EVEN using the Normal Legislative Process, let alone by the kind of underhanded, sneaky, and undemocratic manner being pushed by Representatives Ritter and Linehan.

CONFLICTS - Rep. Ritter / Linehan

Representatives Matt Ritter and Liz Linehan have been spear-heading a rather bizarre, "emergency" push to drastically change current Connecticut vaccine law by removing the Religious Exemption.

Matt Ritter is a partner at Shipman Goodman. Shipman Goodman recently picked up Pharma giant Boehringer Ingelheim as a client to defend it against numerous lawsuits related to one of its drugs.
https://www.law.com/ctlawtribune/2018/10/08/covington-shipman-goodwin-prevail-in-another-defense-of-pradaxa/

A partner who can bring in and/or keep a client like that - the "Holy Grail" of clients for a law firm - can write his own ticket at the firm.

Boehringer Ingelheim is moving into Human Vaccines, including for Hepatitis C and Influenza
https://www.prweb.com/releases/2016/11/prweb13861798.

https://clinicaltrials.gov/ct2/show/NCT01297270

https://drug-dev.com/the-human-vaccines-project-boehringer-ingelheim-partner-to-accelerate-the-development-of-cancer-vaccines-immunotherapies/

https://clinicaltrials.gov/ct2/show/NCT03164772?term=Boehringer+Ingelheim&cond=vaccine&rank=4

https://clinicaltrials.gov/ct2/show/NCT00783380

Moreover, Ritter's father is lobbyist for firm that represents Boehringer Ingelheim.
http://www.brownrudnick.com/people/thomas-d-ritter/

https://www.google.com/amp/s/www.ibtimes.com/political-capital/why-are-drug-prices-going-democratic-power-players-help-pharmaceutical-industry%3famp=1

Rep. Liz Linehan also has a direct connection to Boehringer Ingelheim - her husband is

a SCIENTIST at Boehringer Ingelheim.
http://linkedin.com/in/brian-linehan-b504509

These 2 Reps have been irrationally pushing for a drastic change to current CT law - removing the seldom used "Religious Exemption" for vaccine compliance - and they both financially benefit gigantically from a Vaccine-maker themselves and/or through their families.

Not "Safe"

Let's start by dispensing with the LIE that Vaccines are safe. All we hear from the CDC and the media are that vaccines are "SAFE AND EFFECTIVE." Under no definition of which I am aware are Vaccines SAFE. No drug is. If they were safe, the vaccine makers would NOT feel compelled to list "Adverse Reactions" on the Vaccine package inserts. AND most certainly the federal Vaccine Injury Compensation Fund down in D.C. (The Vaccine Court) wouldn't pay out an AVERAGE of over $110,000,000.00 PER YEAR for Vaccine Injuries, as it does. [And this figure has to be a MINUTE FRACTION of overall Vaccine Injuries, as most people aren't even aware that the Vaccine Injury Compensation Fund exists – it was created by Act of Congress in 1986 after intense lobbying by the Vaccine Makers; they were getting the pants sued off of them after the DTP Vaccine was causing so many injuries.]

I Have also included in my submission the link to the Table of Injuries for the Vaccine Court and the introductory section that talks about the types of injuries listed in the Table – INCLUDING DEATH.

We can certainly have a debate about 'the greater good" and about whether compelled medication is consistent with a free society – but we have to start off being honest.

There are a number of industry-sponsored studies that show the MMR Vaccine is safe. What you will find NOWHERE, however, is a SINGLE STUDY that looks at the safety of injecting our infants and children with SO MANY VACCINES.

In 1983, our children received a GRAND TOTAL of 11 doses of vaccines.

https://www.cdc.gov/vaccines/schedules/images/schedule1983s.jpg

Today, we are supposed to inject our children with well over 50 DOSES, including seasonal Flu. That's 5 times the number of Vaccines – with ALL OF THEIR various adjuvants and ingredients, like ALUMINUM and FORMALDIHYDE.

https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html

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TONG Memo

I have been a practicing criminal defense attorney for 20 years now – and I venture to guess that I have significantly more trial and appellate experience that Mr. TONG: In my opinion there are some serious flaws in his analysis, not least of which is the way in which he glossed over the fact that, in CT, there is a Constitutional Right to FREE PUBLIC EDUCATION, citing a California Appellate case in a footnote, that isn't in any way binding here in CT. I can assure you that our Appellate Courts give greater weight to our Constitution than Mr. Tong is willing to acknowledge.

I can tell you with a 100% certainty that, should Representatives Ritter and Linehan's sham process succeed, there will be at least one Injunction action filed – and while I like my chances, it should never, EVER get to that point given (a) the disgraceful sidestep of the normal democratic process here, and (b) the fact that there is NO OUTBREAK of any kind in CT,

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CDC History – Tuskegee Syphilis Experiment

I have included excerpts from a well-sourced Wikipedia page (link above) about the infamous *Tuskegee Syphilis Experiment*, whereby hundreds of African-American males with syphilis were told they were getting free healthcare from the US Government but, instead, they were purposely NOT treated so that the CDC (a branch of the US Public Health Service) could watch these men throughout their lives to see the effects of UNTREATED SYPHILIS on the human body.

This unthinkable experiment ended not so long ago in late 1972 – and ONLY because its existence had been leaked to the press.

Big 4 Vaccine Makers Can't Be Trusted

The "Big Four" are MERCK, GSK, Pfizer, and Sanofi-Pasteur. In the last 7 years, the first 3 have each paid in the neighborhood of $1 Billion or More to settle claims brought by the US Government of FRAUD, including FRAUDULENT STUDIES and Submission of Fraudulent Data to US Regulatory Agencies. The last, SANOFI, only had to pay about $100 MILLION for its Fraud.

Pharmaceutical Companies are the NUMBER ONE ADVERTISING CLIENT, by FAR, of the media in the US. Anyone paying even the slightest attention can see that PHARMA are using leveraging these miniscule Measles episodes into a NATIONWIDE campaign to ELIMINATE EXEMPTIONS and thereby INCREASE PROFITS.

2 WEEKS ago, Merck announced hire than expected profits in the 1st Quarter based in large part on rising vaccine revenues. "

- Gardasil sales rose 27 percent to $828 million, beating analyst expectations by about $25 million.
- Sales of the company's measles-mumps-rubella and chickenpox vaccines rose 27 percent to $496 million, helped by government tenders in Latin America and higher European and U.S. demand.

https://www.reuters.com/article/us-merck-co-results/merck-raises-full-year-forecasts-as-vaccines-power-profit-beat-idUSKCN1S616K

Stanley Plotkin / Paul Offit

Stanley Plotkin is known as the "Godfather of Modern Vaccines." He literally wrote the book on vaccines.

Last year he was deposed by a New York Attorney, Aaron SIRI (Who I am attempting to recruit to assist should we need to mount a legal challenge) got him to acknowledge information that revealed MAMMOTH Conflicts of Interest for both him and his protégé, PAUL OFFIT, the man maybe most cited in our national media as an "Expert" in vaccines. They each own all or partial interest in one or more of the VACCINES currently contained in the CDC schedule. PLOTKIN worked for Sanofi-Pasteur until 2000 and has been paid by EACH of the "BIG 4" as a consultant to this day.

CLOSE

I urge (even BEG) you all to not do anything RASH here (no pun intended). There is NO PROBLEM that needs fixing at all, let alone by the DRASTIC MEASURE of removing the Religious Exemption that has been in place since Vaccines were mandated in this state 60 years ago – and to do so outside of normal dem channels.

Thank you.

Lindy R. Urso
Cos Cob, CT

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TABLE 1. Recommended schedule for active immunization of normal infants and children (See individual ACIP recommendations for details.)

Recommended age*	Vaccine(s)†	Comments
2 mo.	DTP-1,§ OPV-1¶	Can be given earlier in areas of high endemicity
4 mo.	DTP-2, OPV-2	6-wks-2-mo. interval desired between OPV doses to avoid interference
6 mo.	DTP-3	An additional dose of OPV at this time is optional for use in areas with a high risk of polio exposure
15 mo.**	MMR††	
18 mo.**	DTP-4, OPV-3	Completion of primary series
4-6 yr.§§	DTP-5, OPV-4	Preferably at or before school entry
14-16 yr	Td¶¶	Repeat every 10 years throughout life

*These recommended ages should not be construed as absolute, i.e. 2 mos. can be 6-10 weeks, etc.

†For all products used, consult manufacturer's package enclosure for instructions for storage, handling, and administration. Immunobiologics prepared by different manufacturers may vary, and those of the same manufacturer may change from time to time. The package insert should be followed for a specific product.

§DTP—Diphtheria and tetanus toxoids and pertussis vaccine.

¶OPV—Oral, attenuated poliovirus vaccine contains poliovirus types 1, 2, and 3.

**Simultaneous administration of MMR, DTP, and OPV is appropriate for patients whose compliance with medical care recommendations cannot be assured.

††MMR—Live measles, mumps, and rubella viruses in a combined vaccine (see text for discussion of single vaccines versus combination).

§§Up to the seventh birthday.

¶¶Td—Adult tetanus toxoid and diphtheria toxoid in combination, which contains the same dose of tetanus toxoid as DTP or DT and a reduced dose of diphtheria toxoid.

Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

Immunization Schedules

Always make recommendations by determining needed vaccines based on age (Table 1 (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#birth-15)), determining appropriate intervals for catch-up, if needed (Table 2 (https://www.cdc.gov/vaccines/schedules/hcp/imz/catchup.html)), assessing for medical indications (Table 3 (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-indications.html)), and reviewing special situations (Notes (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#notes)).

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Table 1. By age (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#birth-15)	**Table 2. Catch-up schedule** (https://www.cdc.gov/vaccines/schedules/hcp/imz/catchup.html)	**Table 3. By medical indications** (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-indications.html)	Changes to this year's schedule (https://www.cdc.gov/vaccines/schedules/hcp/schedule-changes.html#child)	Parent-friendly schedule (https://www.cdc.gov/vaccines/schedules/easy-to-read/child-easyread.html)	Resources for health care providers (https://www.cdc.gov/vaccines/schedules/hcp/resources.html)

- 8.5"x11" print color [8 pages] (https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf)
- 8.5"x11" print black and white [8 pages] (https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-combined-schedule-bw.pdf)
- Compliant version of this schedule (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent-compliant.html)

- Vaccines in the Child and Adolescent Immunization Schedule (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#vaccines-schedule)
- Learn how to display current schedules from your website. (https://www.cdc.gov/vaccines/schedules/resource-library/syndicate.html)
- Hard copies of the schedules are available for ordering using the CDC-INFO On Demand ordering form (https://wwwn.cdc.gov/pubs/CDCInfoOnDemand.aspx?ProgramID=84).

(https://www.cdc.gov/vaccines/schedules/hcp/schedule-app.html#download)

Download Schedules App (https://www.cdc.gov/vaccines/schedules/hcp/schedule-app.html#download)

Legend

Range of recommended ages for all children	Range of recommended ages for catch-up immunization	Range of recommended ages for certain high-risk groups	Range of recommended ages for non-high-risk groups that may receive vaccine, subject to individual clinical decision-making	No recommendation

Birth to 15 Months

Vaccine	Birth	1 mo	2 mos	4 mos	6 n
Hepatitis B (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#note-hepb) (https://www.cdc.gov/vaccines/vpd/hepb/hcp/index.html) **(HepB)**	1st dose	2nd dose			
Rotavirus (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#note-rotavirus) (https://www.cdc.gov/vaccines/vpd/rotavirus/hcp/index.html) **(RV) RV1 (2-dose series); RV5 (3-dose series)**			1st dose	2nd dose	See I (https://www.cdc.gov/vaccir adolescent.html
Diphtheria, tetanus, & acellular pertussis (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#note-dtap) (https://www.cdc.gov/vaccines/vpd/dtap-tdap-td/hcp/index.html) **(DTaP: <7 yrs)**			1st dose	2nd dose	3rd (
Haemophilus influenzae *(https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#note-hib)* **type b** (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#hib) (https://www.cdc.gov/vaccines/vpd/hib/hcp/index.html) **(Hib)**			1st dose	2nd dose	See I (https://www.cdc.gov/vaccir adolescent.ht
Pneumococcal conjugate (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#note-pneumo) (https://www.cdc.gov/vaccines/vpd/pneumo/hcp/index.html) **(PCV13)**			1st dose	2nd dose	3rd (
Inactivated poliovirus (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#note-polio) (https://www.cdc.gov/vaccines/vpd/polio/hcp/index.html) **(IPV: <18 yrs)**			1st dose	2nd dose	
Influenza (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#note-flu) **(IIV)** (https://www.cdc.gov/vaccines/vpd/flu/hcp/index.html)					
Influenza (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#note-flu) **(LAIV)** (https://www.cdc.gov/vaccines/vpd/flu/hcp/index.html)					
Measles, mumps, rubella (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#note-mmr) (https://www.cdc.gov/vaccines/vpd/mmr/hcp/index.html) **(MMR)**					(https://www.cdc.gov/v adolesce

Vaccine	Birth	1 mo	2 mos	4 mos	6 n
Varicella (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#note-varicella) (https://www.cdc.gov/vaccines/vpd/varicella/hcp/index.html) **(VAR)**					
Hepatitis A (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#note-hepa) (https://www.cdc.gov/vaccines/vpd/hepa/hcp/index.html) **(HepA)**					(https://www.cdc.gov/v adolesce
Meningococcal (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#note-mening) (https://www.cdc.gov/vaccines/vpd/mening/hcp/index.html) **(MenACWY-D: ≥9 mos; MenACWY-CRM: ≥2 mos)**					See notes (https://ww
Tetanus, diphtheria, & acellular pertussis (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#note-tdap) (https://www.cdc.gov/vaccines/vpd/dtap-tdap-td/hcp/index.html) **(Tdap: ≥7 yrs)**					
Human papillomavirus (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#note-hpv) (https://www.cdc.gov/vaccines/vpd/hpv/hcp/index.html) **(HPV)**					
Meningococcal B (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#note-mening-b) (https://www.cdc.gov/vaccines/vpd/mening/hcp/index.html)**(MenB)**					
Pneumococcal polysaccharide (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#note-pneumo) (https://www.cdc.gov/vaccines/vpd/pneumo/hcp/index.html) **(PPSV23)**					

18 Months to 18 Years

Vaccines	18 mos	19-23 mos	2-3 yrs	4-6 yrs
Hepatitis B (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#note-hepb) (https://www.cdc.gov/vaccines/vpd/hepb/hcp/index.html) **(HepB)**	←3rd dose→			
Rotavirus (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#note-rotavirus) (https://www.cdc.gov/vaccines/vpd/rotavirus/hcp/index.html) **(RV) RV1 (2-dose series); RV5 (3-dose series)**				
Diphtheria, tetanus, & acellular pertussis (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#note-dtap) (https://www.cdc.gov/vaccines/vpd/dtap-tdap-td/hcp/index.html) **(DTaP: <7 yrs)**	←4th dose→			5th dose
Haemophilus influenzae *(https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#note-hib)* **type b** (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#hib) (https://www.cdc.gov/vaccines/vpd/hib/hcp/index.html) **(Hib)**				
Pneumococcal conjugate (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#note-pneumo) (https://www.cdc.gov/vaccines/vpd/pneumo/hcp/index.html) **(PCV13)**				
Inactivated poliovirus (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#note-polio) (https://www.cdc.gov/vaccines/vpd/polio/hcp/index.html) **(IPV: <18 yrs)**	←3rd dose→			4th dose
Influenza (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#note-flu) **(IIV)** (https://www.cdc.gov/vaccines/vpd/flu/hcp/index.html)		Annual vaccination 1 or 2 doses		
Influenza (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#note-flu) **(LAIV)** (https://www.cdc.gov/vaccines/vpd/flu/hcp/index.html)				Annual vaccination 1 or 2 doses

Vaccines	18 mos	19-23 mos	2-3 yrs	4-6 yrs
Measles, mumps, rubella (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#note-mmr) (https://www.cdc.gov/vaccines/vpd/mmr/hcp/index.html) **(MMR)**				2nd dose
Varicella (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#note-varicella) (https://www.cdc.gov/vaccines/vpd/varicella/hcp/index.html) **(VAR)**				2nd dose
Hepatitis A (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#note-hepa) (https://www.cdc.gov/vaccines/vpd/hepa/hcp/index.html) **(HepA)**	← 2-dose series, See notes (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#note-hepa)→			
Meningococcal (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#note-mening) (https://www.cdc.gov/vaccines/vpd/mening/hcp/index.html) **(MenACWY-D: ≥9 mos; MenACWY-CRM: ≥2 mos)**	See notes (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#note-mening)			
Tetanus, diphtheria, & acellular pertussis (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#note-tdap) (https://www.cdc.gov/vaccines/vpd/dtap-tdap-td/hcp/index.html) **(Tdap: ≥7 yrs)**				
Human papillomavirus (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#note-hpv) (https://www.cdc.gov/vaccines/vpd/hpv/hcp/index.html) **(HPV)**				
Meningococcal B (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#note-mening-b) (https://www.cdc.gov/vaccines/vpd/mening/hcp/index.html) **(MenB)**				
Pneumococcal polysaccharide (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#note-pneumo) (https://www.cdc.gov/vaccines/vpd/pneumo/hcp/index.html) **(PPSV23)**				See notes

Top of Page (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#)

Vaccine Injury Table

"Applies Only to Petitions for Compensation Filed under the National Vaccine Injury Compensation Program on or after March 21, 2017 (a) In accordance with section 312(b) of the National Childhood Vaccine Injury Act of 1986, title III of Public Law 99-660, 100 Stat. 3779 (42 U.S.C. 300aa-1 note) and section 2114(c) of the Public Health Service Act, as amended (PHS Act) (42 U.S.C. 300aa-14(c)), **the following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines**, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the Program. Paragraph (b) of this section sets forth additional provisions that are not separately listed in this Table but that constitute part of it. Paragraph (c) of this section sets forth the qualifications and aids to interpretation for the terms used in the Table. Conditions and injuries that do not meet the terms of the qualifications and aids to interpretation are not within the Table. Paragraph (d) of this section sets forth a glossary of terms used in paragraph (c)."

...

https://www.hrsa.gov/sites/default/files/vaccinecompensation/vaccineinjurytable.pdf

Vaccine Excipient & Media Summary

Excipients Included in U.S. Vaccines, by Vaccine

In addition to weakened or killed disease antigens (viruses or bacteria), vaccines contain very small amounts of other ingredients – excipients or media.

Some excipients are added to a vaccine for a specific purpose. These include:
Preservatives, to prevent contamination. For example, thimerosal.
Adjuvants, to help stimulate a stronger immune response. For example, aluminum salts.
Stabilizers, to keep the vaccine potent during transportation and storage. For example, sugars or gelatin.

Others are residual trace amounts of materials that were used during the manufacturing process and removed. These include:
Cell culture materials, used to grow the vaccine antigens. For example, egg protein, various culture media.
Inactivating ingredients, used to kill viruses or inactivate toxins. For example, formaldehyde.
Antibiotics, used to prevent contamination by bacteria. For example, neomycin.

The following table lists all components, other than antigens, shown in the manufacturers' package insert (PI) for each vaccine. Each of these PIs, which can be found on the FDA's website (see below) contains a description of that vaccine's manufacturing process, including the amount and purpose of each substance. In most PIs, this information is found in Section 11: "Description."

All information was extracted from manufacturers' package inserts.
If in doubt about whether a PI has been updated since this table was prepared, check the FDA's website at:
http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm

Vaccine	Contains
Adenovirus	human-diploid fibroblast cell cultures (strain WI-38), Dulbecco's Modified Eagle's Medium, fetal bovine serum, sodium bicarbonate, monosodium glutamate, sucrose, D-mannose, D-fructose, dextrose, human serum albumin, potassium phosphate, plasdone C, anhydrous lactose, microcrystalline cellulose, polacrilin potassium, magnesium stearate, cellulose acetate phthalate, alcohol, acetone, castor oil, FD&C Yellow #6 aluminum lake dye
Anthrax (Biothrax)	amino acids, vitamins, inorganic salts, sugars, aluminum hydroxide, sodium chloride, benzethonium chloride, formaldehyde
BCG (Tice)	glycerin, asparagine, citric acid, potassium phosphate, magnesium sulfate, iron ammonium citrate, lactose
Cholera (Vaxchora)	casamino acids, yeast extract, mineral salts, anti-foaming agent, ascorbic acid, hydrolyzed casein, sodium chloride, sucrose, dried lactose, sodium bicarbonate, sodium carbonate
DT (Sanofi)	aluminum phosphate, isotonic sodium chloride, formaldehyde, casein, cystine, maltose, uracil, inorganic salts, vitamins, dextrose
DTaP (Daptacel)	aluminum phosphate, formaldehyde, glutaraldehyde, 2-phenoxyethanol, Stainer-Scholte medium, casamino acids, dimethyl-beta-cyclodextrin, Mueller's growth medium, ammonium sulfate, modified Mueller-Miller casamino acid medium without beef heart infusion
DTaP (Infanrix)	Fenton medium containing a bovine extract, modified Latham medium derived from bovine casein, formaldehyde, modified Stainer-Scholte liquid medium, glutaraldehyde, aluminum hydroxide, sodium chloride, polysorbate 80 (Tween 80)
DTaP-IPV (Kinrix)	Fenton medium containing a bovine extract, modified Latham medium derived from bovine casein, formaldehyde, modified Stainer-Scholte liquid medium, glutaraldehyde, aluminum hydroxide, VERO cells, a continuous line of monkey kidney cells, Calf serum, lactalbumin hydrolysate, sodium chloride, polysorbate 80 (Tween 80), neomycin sulfate, polymyxin B
DTaP-IPV (Quadracel)	modified Mueller's growth medium, ammonium sulfate, modified Mueller-Miller casamino acid medium without beef heart infusion, formaldehyde, aluminum phosphate, Stainer-Scholte medium, casamino acids, dimethyl-beta-cyclodextrin, MRC-5 cells, normal human diploid cells, CMRL 1969 medium supplemented with calf serum, Medium 199 without calf serum, 2-phenoxyethanol, polysorbate 80, glutaraldehyde, neomycin, polymyxin B sulfate

Vaccine	Contains
DTaP-HepB-IPV (Pediarix)	Fenton medium containing a bovine extract, modified Latham medium derived from bovine casein, formaldehyde, glutaraldehyde, modified Stainer-Scholte liquid medium, VERO cells, a continuous line of monkey kidney cells, calf serum and lactalbumin hydrolysate, aluminum hydroxide, aluminum phosphate, aluminum salts, sodium chloride, polysorbate 80 (Tween 80), neomycin sulfate, polymyxin B, yeast protein.
DTaP-IPV/Hib (Pentacel)	aluminum phosphate, polysorbate 80, sucrose, formaldehyde, glutaraldehyde, bovine serum albumin, 2-phenoxyethanol, neomycin, polymyxin B sulfate, modified Mueller's growth medium, ammonium sulfate, modified Mueller-Miller casamino acid medium without beef heart infusion, Stainer-Scholte medium, casamino acids, dimethyl-beta-cyclodextrin. MRC-5 cells (a line of normal human diploid cells), CMRL 1969 medium supplemented with calf serum, Medium 199 without calf serum, modified Mueller and Miller medium
Hib (ActHIB)	sodium chloride, modified Mueller and Miller medium (the culture medium contains milk-derived raw materials [casein derivatives]), formaldehyde, sucrose
Hib (Hiberix)	saline, synthetic medium, formaldehyde, sodium chloride, lactose
Hib (PedvaxHIB)	complex fermentation media, amorphous aluminum hydroxyphosphate sulfate, sodium chloride
Hep A (Havrix)	MRC-5 human diploid cells, formalin, aluminum hydroxide, amino acid supplement, phosphate-buffered saline solution, polysorbate 20, neomycin sulfate, aminoglycoside antibiotic
Hep A (Vaqta)	MRC-5 diploid fibroblasts, amorphous aluminum hydroxyphosphate sulfate, non-viral protein, DNA, bovine albumin, formaldehyde, neomycin, sodium borate, sodium chloride
Hep B (Engerix-B)	aluminum hydroxide, yeast protein, sodium chloride, disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate
Hep B (Recombivax)	soy peptone, dextrose, amino acids, mineral salts, phosphate buffer, formaldehyde, potassium aluminum sulfate, amorphous aluminum hydroxyphosphate sulfate, yeast protein
Hep B (Heplisav-B)	vitamins and mineral salts, yeast protein, yeast DNA, deoxycholate, phosphorothioate linked oligodeoxynucleotide, phosphate buffered saline, sodium phosphate, dibasic dodecahydrate, monobasic dehydrate, polysorbate 80
Hep A/Hep B (Twinrix)	MRC-5 human diploid cells, formalin, aluminum phosphate, aluminum hydroxide, amino acids, sodium chloride, phosphate buffer, polysorbate 20, neomycin sulfate, yeast protein
Human Papillomavirus (HPV) (Gardasil 9)	vitamins, amino acids, mineral salts, carbohydrates, amorphous aluminum hydroxyphosphate sulfate, sodium chloride, L-histidine, polysorbate 80, sodium borate, yeast protein
Influenza (Afluria) Trivalent & Quadrivalent	sodium chloride, monobasic sodium phosphate, dibasic sodium phosphate, monobasic potassium phosphate, potassium chloride, calcium chloride, sodium taurodeoxycholate, ovalbumin, sucrose, neomycin sulfate, polymyxin B, beta-propiolactone, thimerosal (multi-dose vials)
Influenza (Fluad)	squalene, polysorbate 80, sorbitan triolcate, sodium citrate dehydrate, citric acid monohydrate, neomycin, kanamycin, barium, egg proteins, cetyltrimethylammonium bromide (CTAB), formaldehyde
Influenza (Fluarix) Quadrivalent	octoxynol-10 (TRITON X-100), α-tocopheryl hydrogen succinate, polysorbate 80 (Tween 80), hydrocortisone, gentamicin sulfate, ovalbumin, formaldehyde, sodium deoxycholate, sodium phosphate-buffered isotonic sodium chloride
Influenza (Flublok) Quadrivalent	sodium chloride, monobasic sodium phosphate, dibasic sodium phosphate, polysorbate 20 (Tween 20), baculovirus and *Spodoptera frugiperda* cell proteins, baculovirus and cellular DNA, Triton X-100, lipids, vitamins, amino acids, mineral salts
Influenza (Flucelvax) Quadrivalent	Madin Darby Canine Kidney (MDCK) cell protein, phosphate buffered saline, protein other than HA, MDCK cell DNA, polysorbate 80, cetyltrimethlyammonium bromide, and β-propiolactone, Thimerosal (multi-dose vials)
Influenza (Flulaval) Quadrivalent	ovalbumin, formaldehyde, sodium deoxycholate, α-tocopheryl hydrogen succinate, polysorbate 80, thimerosal (multi-dose vials), phosphate-buffered saline solution
Influenza (Fluzone) Quadrivalent	formaldehyde, egg protein, octylphenol ethoxylate (Triton X-100), sodium phosphate-buffered isotonic sodium chloride solution, thimerosal (multi-dose vials)

Vaccine	Contains
Influenza (Fluzone) High Dose	egg protein, octylphenol ethoxylate (Triton X-100), sodium phosphate-buffered isotonic sodium chloride solution, formaldehyde
Influenza (FluMist) Quadrivalent	monosodium glutamate, hydrolyzed porcine gelatin, arginine, sucrose, dibasic potassium phosphate, monobasic potassium phosphate, ovalbumin, gentamicin sulfate, ethylenediaminetetraacetic acid (EDTA)
Japanese Encephalitis (Ixiaro)	aluminum hydroxide, protamine sulfate, formaldehyde, bovine serum albumin, host cell DNA, sodium metabisulphite, host cell protein
Meningococcal (MenACWY-Menactra)	Watson Scherp media containing casamino acid, modified culture medium containing hydrolyzed casein, ammonium sulfate, sodium phosphate, formaldehyde, sodium chloride
Meningococcal (MenACWY-Menveo)	formaldehyde, amino acids, yeast extract, Franz complete medium, CY medium
Meningococcal (MenB – Bexsero)	aluminum hydroxide, *E. coli*, histidine, sucrose, deoxycholate, kanamycin
Meningococcal (MenB – Trumenba)	defined fermentation growth media, polysorbate 80, aluminum phosphate, histidine buffered saline
MMR (MMR-II)	chick embryo cell culture, WI-38 human diploid lung fibroblasts, vitamins, amino acids, fetal bovine serum, sucrose, glutamate, recombinant human albumin, neomycin, sorbitol, hydrolyzed gelatin, sodium phosphate, sodium chloride
MMRV (ProQuad) (Frozen)	chick embryo cell culture, WI-38 human diploid lung fibroblasts, MRC-5 cells, sucrose, hydrolyzed gelatin, sodium chloride, sorbitol, monosodium L-glutamate, sodium phosphate dibasic, human albumin, sodium bicarbonate, potassium phosphate monobasic, potassium chloride; potassium phosphate dibasic, neomycin, bovine calf serum
MMRV (ProQuad) (Refrigerator Stable)	chick embryo cell culture, WI-38 human diploid lung fibroblasts, MRC-5 cells, sucrose, hydrolyzed gelatin, urea, sodium chloride, sorbitol, monosodium L-glutamate, sodium phosphate, recombinant human albumin, sodium bicarbonate, potassium phosphate, potassium chloride, neomycin, bovine serum albumin
Pneumococcal (PCV13 – Prevnar 13)	soy peptone broth, casamino acids and yeast extract-based medium, CRM197 carrier protein, polysorbate 80, succinate buffer, aluminum phosphate
Pneumococcal (PPSV-23 – Pneumovax)	phenol
Polio (IPV – Ipol)	Eagle MEM modified medium, calf bovine serum, M-199 without calf bovine serum, vero cells (a continuous line of monkey kidney cells), phenoxyethanol, formaldehyde, neomycin, streptomycin, polymyxin B
Rabies (Imovax)	human albumin, neomycin sulfate, phenol red indicator, MRC-5 human diploid cells, beta-propriolactone
Rabies (RabAvert)	chicken fibroblasts, β-propiolactone, polygeline (processed bovine gelatin), human serum albumin, bovine serum, potassium glutamate, sodium EDTA, ovalbumin, neomycin, chlortetracycline, amphotericin B
Rotavirus (RotaTeq)	sucrose, sodium citrate, sodium phosphate monobasic monohydrate, sodium hydroxide, polysorbate 80, cell culture media, fetal bovine serum, vero cells *[DNA from porcine circoviruses (PCV) 1 and 2 has been detected in RotaTeq. PCV-1 and PCV-2 are not known to cause disease in humans.]*
Rotavirus (Rotarix)	Vero cells, dextran, Dulbecco's Modified Eagle Medium (sodium chloride, potassium chloride, magnesium sulfate, ferric (III) nitrate, sodium phosphate, sodium pyruvate, D-glucose, concentrated vitamin solution, L-cystine, L-tyrosine, amino acids solution, L-glutamine, calcium chloride, sodium hydrogenocarbonate, and phenol red), sorbitol, sucrose, calcium carbonate, sterile water, xanthan *[Porcine circovirus type 1 (PCV-1) is present in Rotarix. PCV-1 is not known to cause disease in humans.]*
Smallpox (Vaccinia) (ACAM2000)	African Green Monkey kidney (Vero) cells, HEPES, 2% human serum albumin, 0.7% sodium chloride USP, 5% Mannitol USP, neomycin, polymyxin B, 50% Glycerin USP, 0.25% phenol USP
Td (Tenivac)	aluminum phosphate, formaldehyde, modified Mueller-Miller casamino acid medium without beef heart infusion, ammonium sulfate, sodium chloride, water

Vaccine	Contains
Td (Mass Biologics)	aluminum phosphate, formaldehyde, thimerosal, modified Mueller's media which contains bovine extracts, ammonium sulfate
Tdap (Adacel)	aluminum phosphate, formaldehyde, 2-phenoxyethanol, Stainer-Scholte medium, casamino acids, dimethyl-beta-cyclodextrin, glutaraldehyde, modified Mueller-Miller casamino acid medium without beef heart infusion, ammonium sulfate, modified Mueller's growth medium
Tdap (Boostrix)	modified Latham medium derived from bovine casein, Fenton medium containing a bovine extract, formaldehyde, modified Stainer-Scholte liquid medium, glutaraldehyde, aluminum hydroxide, sodium chloride, polysorbate 80
Typhoid (Typhim Vi)	hexadecyltrimethylammonium bromide, formaldehyde, phenol, polydimethylsiloxane, disodium phosphate, monosodium phosphate, semi-synthetic medium, sodium chloride, sterile water
Typhoid (Vivotif Ty21a)	yeast extract, casein, dextrose, galactose, sucrose, ascorbic acid, amino acids, lactose, magnesium stearate. gelatin
Varicella (Varivax) *Frozen*	MRC-5 human diploid cells, including DNA & protein, sucrose, hydrolyzed gelatin, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, sodium phosphate monobasic, potassium phosphate monobasic, potassium chloride, EDTA, neomycin, fetal bovine serum
Varicella (Varivax) *Refrigerator Stable*	MRC-5 human diploid cells, including DNA & protein, sucrose, hydrolyzed gelatin, sodium chloride, monosodium L-glutamate, urea, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride, neomycin, bovine calf serum
Yellow Fever (YF-Vax)	sorbitol, gelatin, sodium chloride, egg protein
Zoster (Shingles) (Zostavax) *Frozen*	MRC-5 human diploid cells, including DNA & protein, sucrose, hydrolyzed porcine gelatin, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride; neomycin, bovine calf serum
Zoster (Shingles) (Zostavax) *Refrigerator Stable*	MRC-5 human diploid cells, including DNA & protein, sucrose, hydrolyzed porcine gelatin, urea, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride, neomycin, bovine calf serum
Zoster (Shingles) (Shingrix)	sucrose, sodium chloride, dioleoyl phosphatidylcholine (DOPC), 3-*O*-desacl-4'monophosphoryl lipid A (MPL), QS-21 (a saponin purified from plant extract *Quillaja saponaria* Molina), potassium dihydrogen phosphate, cholesterol, sodium dihydrogen phosphate dihydrate, disodium phosphate anhydrous, dipotassium phosphate, polysorbate 80

A table listing vaccine excipients and media *by excipient* is published by the Institute for Vaccine Safety at Johns Hopkins University, and can be found at http://www.vaccinesafety.edu/components-Excipients.htm.

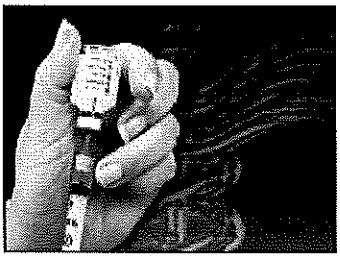
Updates:

Trumenba: (added Aluminum phosphate)
RotaTeq: PI dated 2/2017
Rotarix: 6/11/18 (PI dated xx/xxxx)
Smallpox: 3/2018
Td (Tenivac): April 2013
Td (Mass Biologics): April 2009 (no change)
Tdap (Adacel): xxx/2017 (no change)
Tdap (Boostrix): 6/12/2018 (PI dated xx/xxxx) (no change)
Typhim Vi: March 2014 (added sodium chloride & buffered saline)
Ty21a: September 2013
Varicella Frozen: 2/2017
Varicella Refrigerator Stable: 2/2017
YF Vax: June 2016
Zostivax Frozen: xx/2018
Zostivax Refrigerator Stable: xx/2018
Shingrix: 10/2017

LIVE

Vaccine Court

BY SHARYL ATTKISSON
JUNE 27, 2008 / 9:52 AM / CBS NEWS



(AP)

Most Americans have probably never heard of it, but there is a special federal court that was set up to compensate victims and their families for vaccine injuries. This "vaccine court" has been functioning since 1988. Its genesis can be found on the Center for Disease Control and Prevention government Web page, National Vaccine Program Office.

In summary, in the early 1980's, there were so many claims of injuries from DTP vaccine (which has since been replaced with what officials believe is a safer version of the vaccine: DTaP), that vaccine makers told Congress they wouldn't be able to produce vaccines unless they were protected from liability. Members of Congress and public health officials worried that unless vaccine makers were somehow protected, they would stop producing vaccines and the public health would be threatened. The result was vaccine court. The concept was put together with help from government, vaccine makers and the public. Victims can receive compensation in a streamlined process. Vaccine makers don't have to bear the cost. Instead, damages are paid by the public through a 75-cent tax we pay on each dose of vaccine administered. All sides in the controversies over

vaccine safety would probably agree that vaccine court isn't perfect, but despite some of its flaws, it is generally widely praised.

Unfortunately, vaccine court is little-known. It's believed only a small fraction of the total number of claims ever makes its way to this court. In my reporting, I often ask families who believe their children were injured by vaccines whether they've filed a claim in vaccine court. None of them had ever heard of this court. Several said something like, "How would we ever have time to pursue such a thing? We're spending all our time trying to care for our injured child."

Nonetheless, the cases that do make it to vaccine court have the potential to provide valuable information as to possible trends that could be happening in the public at large. More than a billion dollars has been paid out to vaccine victims since the court opened its doors in Washington D.C. back in 1988. Statistics regarding the number of claims filed, won, and denied broken down by vaccine type can be found here. Be aware that the raw numbers aren't particularly reflective of much since so few cases make their way to vaccine court.

Trending News

- Generic Drug Makers
- Trump's China Tariffs
- Mother's Day
- Central Park Five

The following information is from Health Resources and Services Administration (HRSA):

"For nearly 20 years, the National Vaccine Injury Compensation Program (VICP) has provided children and families compassionate, generous, and timely compensation in rare instances of vaccine injury.

The program allows injured individuals to seek compensation in a special court without cost to them. Certain injuries are presumed to have been caused or aggravated by the vaccine, and are on a table of injuries. If the injury is found to be consistent with a table injury without sufficient evidence of another cause, the family would be compensated. Injury cases not included on the current table also can be compensated if there is sufficient proof that they were caused by the vaccine.

The CDC's Tuskegee Syphilis Experiment.

https://en.wikipedia.org/wiki/Tuskegee_syphilis_experiment

The following are excerpts from a well-sourced Wikipedia page (link above) about the infamous *Tuskegee Syphilis Experiment*, whereby hundreds of African-American males with syphilis were told they were getting free healthcare from the US Government but, instead, they were purposely NOT treated so that the CDC (a branch of the US Public Health Service) could watch these men throughout their lives to see the effects of UNTREATED SYPHILIS on the human body.

As you will see below, the unthinkable experiment ended in 1972 – and ONLY because its existence had been leaked to the press.

"The **Tuskegee Study of Untreated Syphilis in the Negro Male** was an infamous and unethical clinical study conducted between 1932 and 1972 by the U.S. Public Health Service. The purpose of this study was to observe the natural history of untreated syphilis; the African-American men in the study were told they were receiving free health care from the United States government."

"The men were given free medical care, meals, and free burial insurance for participating in the study. The men were told that the study was only going to last six months, but it actually lasted 40 years.[2] After funding for treatment was lost, the study was continued without informing the men that they would never be treated. None of the men were told that they had the disease, and none were treated with penicillin even after the antibiotic was proven to successfully treat syphilis."

"By 1947, penicillin had become the standard treatment for syphilis. Choices available to the doctors involved in the study might have included treating all syphilitic subjects and closing the study, or splitting off a control group for testing with penicillin. Instead, the Tuskegee scientists continued the study without treating any participants; they withheld penicillin and information about it from the patients. In addition, scientists prevented participants from accessing syphilis treatment programs available to other residents in the area.[6] The study continued, under numerous US Public Health Service supervisors, until 1972, when a leak to the press resulted in its termination on November 16 of that year.[7]The victims of the study, all African American, included numerous men who died of syphilis, 40 wives who contracted the disease, and 19 children born with congenital syphilis."

"In 1966 Peter Buxtun, a PHS venereal-disease investigator in San Francisco, sent a letter to the national director of the Division of Venereal Diseases to express his concerns about the ethics and morality of the extended Tuskegee Study. The Center for Disease Control (CDC), which by then controlled the study, reaffirmed the need to continue the study until completion; i.e., until all subjects had died and been autopsied."

JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE Tuesday, November 22, 2011

U.S. Pharmaceutical Company Merck Sharp & Dohme to Pay Nearly One Billion Dollars Over Promotion of Vioxx®

Merck to Pay $950 Million for Illegal Marketing

WASHINGTON – American pharmaceutical company Merck, Sharp & Dohme has agreed to pay $950 million to resolve criminal charges and civil claims related to its promotion and marketing of the painkiller Vioxx® (rofecoxib), the Justice Department announced today. Under the terms of the resolution, Merck will plead guilty to a one-count information charging a single violation of the Food Drug and Cosmetic Act (FDCA) for introducing a misbranded drug, Vioxx®, into interstate commerce. Under the terms of its plea agreement with the United States, Merck will plead guilty to a misdemeanor for its illegal promotional activity and will pay a $321,636,000 criminal fine.

Merck is also entering into a civil settlement agreement under which it will pay $628,364,000 to resolve additional allegations regarding off-label marketing of Vioxx® and false statements about the drug's cardiovascular safety. Of the total civil settlement, $426,389,000 will be recovered by the United States, and the remaining share of $201,975,000 will be distributed to the participating Medicaid states. The settlement and plea conclude a long-running investigation of Merck's promotion of Vioxx®, which was withdrawn from the marketplace in September 2004.

Merck's criminal plea relates to misbranding of Vioxx® by promoting the drug for treating rheumatoid arthritis, before that use was approved by the Food and Drug Administration (FDA). Under the provisions of the FDCA, a company is required to specify the intended uses of a product in its new drug application to FDA. Once approved, the drug may not be marketed or promoted for so-called "off-label" uses – any use not specified in an application and approved by FDA – unless the company applies to the FDA for approval of the additional use. The FDA approved Vioxx® for three indications in May 1999, but did not approve its use against rheumatoid arthritis until April 2002. In the interim, for nearly three years, Merck promoted Vioxx® for rheumatoid arthritis, conduct for which it was admonished in an FDA warning letter issued in September 2001.

The parallel civil settlement covers a broader range of allegedly illegal conduct by Merck. The settlement resolves allegations that Merck representatives made inaccurate, unsupported, or misleading statements about Vioxx's cardiovascular safety in order to increase sales of the drug, resulting in payments by the federal government. It also resolves allegations that Merck made false statements to state Medicaid agencies about the cardiovascular safety of Vioxx, and that those agencies relied on Merck's false claims in making payment decisions about the drug. Finally, like the criminal plea, the civil settlement also recovers damages for allegedly false claims caused by Merck's unlawful promotion of Vioxx for rheumatoid arthritis.

"When a pharmaceutical company ignores FDA rules aimed at keeping our medicines safe and effective, that company undermines the ability of health care providers to make the best medical decisions on behalf of their patients," said Tony West, Assistant Attorney General for the Civil Division of the Department of Justice. "As this plea agreement and civil

JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE Monday, July 2, 2012

GlaxoSmithKline to Plead Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data

Largest Health Care Fraud Settlement in U.S. History

Global health care giant GlaxoSmithKline LLC (GSK) agreed to plead guilty and to pay $3 billion to resolve its criminal and civil liability arising from the company's unlawful promotion of certain prescription drugs, its failure to report certain safety data, and its civil liability for alleged false price reporting practices, the Justice Department announced today. The resolution is the largest health care fraud settlement in U.S. history and the largest payment ever by a drug company.

GSK agreed to plead guilty to a three-count criminal information, including two counts of introducing misbranded drugs, Paxil and Wellbutrin, into interstate commerce and one count of failing to report safety data about the drug Avandia to the Food and Drug Administration (FDA). Under the terms of the plea agreement, GSK will pay a total of $1 billion, including a criminal fine of $956,814,400 and forfeiture in the amount of $43,185,600. The criminal plea agreement also includes certain non-monetary compliance commitments and certifications by GSK's U.S. president and board of directors. GSK's guilty plea and sentence is not final until accepted by the U.S. District Court.

GSK will also pay $2 billion to resolve its civil liabilities with the federal government under the False Claims Act, as well as the states. The civil settlement resolves claims relating to Paxil, Wellbutrin and Avandia, as well as additional drugs, and also resolves pricing fraud allegations.

"Today's multi-billion dollar settlement is unprecedented in both size and scope. It underscores the Administration's firm commitment to protecting the American people and holding accountable those who commit health care fraud," said James M. Cole, Deputy Attorney General. "At every level, we are determined to stop practices that jeopardize patients' health, harm taxpayers, and violate the public trust – and this historic action is a clear warning to any company that chooses to break the law."

"Today's historic settlement is a major milestone in our efforts to stamp out health care fraud," said Bill Corr, Deputy Secretary of the Department of Health and Human Services (HHS). "For a long time, our health care system had been a target for cheaters who thought they could make an easy profit at the expense of public safety, taxpayers, and the millions of Americans who depend on programs like Medicare and Medicaid. But thanks to strong enforcement actions like those we have announced today, that equation is rapidly changing."

JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE Wednesday, September 2, 2009

Justice Department Announces Largest Health Care Fraud Settlement in Its History

Pfizer to Pay $2.3 Billion for Fraudulent Marketing

WASHINGTON – American pharmaceutical giant Pfizer Inc. and its subsidiary Pharmacia & Upjohn Company Inc. (hereinafter together "Pfizer") have agreed to pay $2.3 billion, the largest health care fraud settlement in the history of the Department of Justice, to resolve criminal and civil liability arising from the illegal promotion of certain pharmaceutical products, the Justice Department announced today.

Pharmacia & Upjohn Company has agreed to plead guilty to a felony violation of the Food, Drug and Cosmetic Act for misbranding Bextra with the intent to defraud or mislead. Bextra is an anti-inflammatory drug that Pfizer pulled from the market in 2005. Under the provisions of the Food, Drug and Cosmetic Act, a company must specify the intended uses of a product in its new drug application to FDA. Once approved, the drug may not be marketed or promoted for so-called "off-label" uses – *i.e.*, any use not specified in an application and approved by FDA. Pfizer promoted the sale of Bextra for several uses and dosages that the FDA specifically declined to approve due to safety concerns. The company will pay a criminal fine of $1.195 billion, the largest criminal fine ever imposed in the United States for any matter. Pharmacia & Upjohn will also forfeit $105 million, for a total criminal resolution of $1.3 billion.

In addition, Pfizer has agreed to pay $1 billion to resolve allegations under the civil False Claims Act that the company illegally promoted four drugs – Bextra; Geodon, an anti-psychotic drug; Zyvox, an antibiotic; and Lyrica, an anti-epileptic drug – and caused false claims to be submitted to government health care programs for uses that were not medically accepted indications and therefore not covered by those programs. The civil settlement also resolves allegations that Pfizer paid kickbacks to health care providers to induce them to prescribe these, as well as other, drugs. The federal share of the civil settlement is $668,514,830 and the state Medicaid share of the civil settlement is $331,485,170. This is the largest civil fraud settlement in history against a pharmaceutical company.

As part of the settlement, Pfizer also has agreed to enter into an expansive corporate integrity agreement with the Office of Inspector General of the Department of Health and Human Services. That agreement provides for procedures and reviews to be put in place to avoid and promptly detect conduct similar to that which gave rise to this matter.

Whistleblower lawsuits filed under the *qui tam* provisions of the False Claims Act that are pending in the District of Massachusetts, the Eastern District of Pennsylvania and the Eastern District of Kentucky triggered this investigation. As a part of today's resolution, six whistleblowers will receive payments totaling more than $102 million from the federal share of the civil recovery.

The U.S. Attorney's offices for the District of Massachusetts, the Eastern District of Pennsylvania, and the Eastern District of Kentucky, and the Civil Division of the Department of Justice handled these cases. The U.S. Attorney's Office for the District of Massachusetts led the criminal investigation of Bextra. The investigation was conducted by the Office of Inspector General for the Department of Health and Human Services (HHS), the FBI, the Defense Criminal Investigative Service (DCIS), the Office of Criminal Investigations for the Food and Drug Administration (FDA), the Veterans' Administration's (VA) Office of Criminal Investigations, the Office of the Inspector General for the Office of Personnel Management (OPM), the Office of the Inspector General for the United States Postal Service (USPS), the National Association of Medicaid Fraud Control Units and the offices of various state Attorneys General.