Cause for Alarm!

EPA Exempts and USDA Funds - Experimental Aerial Pesticide Spraying On California Residential Population

On 09/09/07- 09/11/07 and 10/24/07 – 10/26/07 from 8pm to 5am each night, an untested pesticide was aerially sprayed on approximately 100,000 citizens on the Monterey Peninsula of the Central Coast of California from airplanes flying below 500 feet. The stated purpose of the spraying is purported to be the control of an invasive pest called the Light Brown Apple Moth (LBAM). The moth has not caused any documented crop damage in California and is of no threat to humans. The moth has lived in Hawaii for over 100 years causing no harm to crops. Australia has also struggled with the LBAM and has neither had their agricultural commodities threatened or devastated by the moth nor been successful in "eradicating" it.

The aerial chemicals chosen by the California Department of Food and Agriculture to eradicate the LBAM are Checkmate OLR-F and Checkmate LBAM manufactured by Suterra, LLC of Bend, OR. They are both slow release microcapsules – a synthetic moth pheromone surrounded in a polymer (plastic) shell - intended to release the pesticide into the air slowly over 30 to 70 days and disrupt the mating cycle of the LBAM. The target areas which will be sprayed are only residential areas. In the "eradication plan" set forth by the California Department of Food and Agriculture there are only plans to spray residential areas, no crops will be sprayed. Further aerial spraying is set to take place 11/04/07 – 11/10/07 in Santa Cruz County, California, and then set to resume monthly, for nine months, beginning in March of 2008 and is approved through 2010.

This project is approved by the EPA and is technically a scientific experiment in that there have never been ANY tests of the completed Checkmate OLR-F Checkmate LBAM products on any living or non-living organisms, until they were sprayed over citizens in Monterey County. This fact was confirmed by the California Department of Agriculture's advisory panel which has been hosting "town hall" meetings focused on "educating" the public about the eradication project. Under heavy questioning by local citizens (by three different citizens) on Tuesday October 23rd, 2007 at the University Inn in Santa Cruz, CA John Connell, Director of Plant Health and Pest Prevention Services admitted that there are no tests of any kind on the completed Checkmate products which have already been sprayed and will be sprayed in the Monterey Peninsula area. A search of the global scientific literature confirms that pheromones for the LBAM have never been tested for aerial applications for safety, or efficacy. What is of deep alarm is that there are no plans to halt or postpone spraying to do additional testing, even though legislators like Assemblyman John Laird have requested them in writing, more than once.

The spraying is carried out by the California Department of Food and Agriculture under an "emergency exemption" (or Section 18) of the California Environmental Quality Act by the Secretary of the Department of Agriculture A.G. Kawamura. The emergency exemption and approval of the safety of

Checkmate was provided by the US Environmental Protection Agency. The majority of funding for the aerial spraying was funneled through the US Department of Food and Agriculture and originated from the Department of Homeland Security. This project's "emergency" exemption status is approved through the year 2010.

Several local city councils in Monterey County unanimously opposed the aerial spraying but voted not to file a law suit because of their perception that there was not enough scientific evidence or a medical doctor to testify in court. Their opinion was also swayed by the CDFA's campaign and presentation tactics, which contained many unscientific facts, unproven theories and omissions that made it sound convincingly like there should not be cause for alarm. A local non-profit organization Helping Our Peninsula's Environment (H.O.P.E) filed suit in the Monterey County Superior Court and was granted a Temporary Restraining Order after Judge Robert O'Farrell reviewed the disconcerting list of ingredients which had been leaked by the Santa Cruz Sentinel newspaper. One week later the same, Judge O'Farrell, hurried the suit out of court and lifted the TRO after sidestepping the in-depth scientific report by a former EPA, PhD chemist which described the likely negative health effects of the ingredients on people, animals and the environment. Judge O'Farrell ruled that if the CDFA would set up a monitoring plan he would not stop the spraying. No health and safety monitoring was set up before the spraying resumed in Monterey County on Oct. 24th and furthermore there was no retroactive monitoring of the health complaints filed in September after the first spray. There was no air quality monitoring and no water testing for the inert ingredients or for particle pollution from the micro-flakes and microcapsules in Checkmate.

Severe side effects were documented in over 200 citizens, including 3 who were hospitalized for severe reaction to the September spraying. Several other residents rushed to the emergency room because of their reaction to the spray. The effects of the aerial application of Checkmate OLR-F and Checkmate LBAM on humans range from eye, nose and throat irritation, to reproductive disorders, to a child nearly dying from asphyxiation. The CDFA has not investigated these health complaints or contacted citizens in any manner, and yet spraying continues. Health effects are noted not just by people sprayed, but by those who enter the Monterey County vicinity after spraying. There are more reports of citizens reacting to the second round of spraying which commenced on Oct. 24th, as well. Many residents during both sprayings left the area to avoid health effects, yet many residents remain unaware of the project at all.

Please note that doctors in the Monterey Peninsula region are refusing to sign affidavits indicating that they believe the spray is related to the health effects seen in individuals. The doctor for an 11 month old boy who almost died refused to sign a statement saying there was a "possible" relationship between the spray and his inability to breathe, even though he had no previous history of airway or lung disorders. The refusal to sign was not because they did not believe that the pesticide caused the illness, but for fear of legal action, or perhaps worse. This infant now has documented long-term damage to both of his lungs. Still his doctors refuse to comment. When questioned by a gentleman representing the family of the 11 month old boy at the same Oct. 23rd meeting in Santa Cruz,

Secretary AG Kawamura stated that he would stop the spraying if he knew that it would harm one child. Neither of the child's doctors (at either hospital where he was treated) will speak with or assist the family in documenting their child's medical case. Thus Secretary Kawamura can hide behind the false shield and claim that no evidence exists of harm from Checkmate. The truth is really the opposite, no evidence exists for the safety of Checkmate!

The slow release microcapsules, flakes, and pheromones in the Checkmate products are not compatible with human physiology, and are responsible for particle pollution. Although the capsules themselves are 80-150 microns, broken, abraded, and malformed capsules produce polymer dust or fine particulate matter. Furthermore, the microcapsules may contain a micro pore system, and a micro sphere system for releasing the pheromones which would likely contain particles in the 2.5 - 10 micron range, a range that is dangerous to humans. But we do not know, because the structure of the microcapsules is kept a secret. According to the American Lung Association, particle pollution is documented as a cause of symptoms such as asthma and severe breathing difficulties in children There are presidential orders written to protect children's health from particle pollution and pesticides do to the acknowledged several times higher risk of infants and children for exposure to chemicals and pollution. These orders have not been appropriately addressed by any party involved.

Further research on the recently published ingredients of Checkmate LBAM reveal that it contains many dangerous substances, including a xenochemical called 2-hydroxy-4-n-octyloxybenzophenone. This chemical acts like a hormone and bonds to estrogen receptors in humans. It is likely to be the cause reproductive system issues reported by women who inhaled the time-release particles. Symptoms in these women consisted of: exacerbated PMS symptoms, swollen and tender breasts, irregular menstrual cycles, and women who had been successfully treating menopause symptoms who suddenly saw their symptoms worsen.

The CDFA, EPA, and USDA all claim Checkmate is a safe Bt class pesticide, for both humans and the environment. They also claim that aerial treatments are the only and final solution to the LBAM "emergency." However, effective methods other than aerial spraying to eliminate the LBAM do exist for agriculture. No tested technology exists, for containing the LBAM in populated areas. Even still, other methods, like pheromone dispensers, sticky traps, and twist ties along with localized ground spraying are the only proven methods to have any effect against LBAM. Aerial applications are not proven to work, since they have not been tested in agricultural, or in populated areas. When the CDFA claims that treatments have been tested, they are referring to ground based spraying, which covers the affected agriculture in a totally different, and more thorough manner, than aerial spraying. Such ground spraying, even on some of the LBAM's favorite foods, like grapes, is done only once per year in Australian vineyards, as the one application is highly effective. Additionally, long lasting twist ties could be placed over thousands of acres, for similar costs to the aerial spraying in approximately 2 weeks time by a large team of workers.

"The use of aerially applied Checkmate OLR-F or LBAM-F has never been tested for efficacy against LBAM. There has never been a successful eradication of a pest using any pheromone unilaterally. The state has no scientific basis to claim that this spray formulation will work. The only published science and, indeed, the only use of pheromone against LBAM has been with Isomate, the twist tie formulation. This work was done in Australia by Suckling and Clearwater. When contacting people who have worked with LBAM in the infested parts of the world, no one describes it as a severe pest. In fact, it is another in a long list of leaf roller (Tortricid) species that are usually easily controlled in agricultural crops. There are no examples of "ecological destruction" by LBAM as reported by folks who have worked on the pest. In short, the eradication program's use of aerially applied Checkmate pheromones is an experiment."

Professional Entomologist
Report Given on the Condition of Anonymity

CDFA claims that these methods are too costly to pursue. Citizens have repeatedly offered their own time and energy in placing traps and twist ties throughout the community to cut costs. The CDFA refuses to comment on that offer. The last aerial application of Checkmate LBAM on the Monterey Peninsula cost $3.7 million, with $3 million being paid directly to Suterra, LLC. Suterra, LLC is owned by the Resnick family which is the largest land- owning family in the United States and a top contributor to the Schwarzenegger campaign.

Citizens were sprayed with the declared “safe” aerial pesticide for several nights against their will. This is a human rights violation and a violation of the State constitutional right to safety and of the Federal constitutional right of personal liberty. The EPA even put a lie on their webpage to support this endeavor. After Monterey Judge Robert O’Farrell stated that he temporarily halted the spray because of the possible presence of an isocyanate, the EPA announced that it had reviewed the original list of ingredients leaked by them the previous week and that there was no isocyanate. In court documents, Suterra representatives acknowledged that the isocyanate PPI was a starting ingredient in Checkmate, so the company said it was in there, but the EPA changed its mind and said it wasn’t.

Aerial Applications Constitute Human Pesticide and Medical Experimentation

“In August 2005, Congress enacted a moratorium upon the EPA using human pesticide experiments until strict ethical standards were established. The intent of this moratorium was to protect pregnant women, and infants from any sort of testing.” The moratorium state, that “Such rule shall not permit the use of pregnant women, infants or children as subjects; shall be consistent with the principles proposed in the 2004 report of the National Academy of Sciences on intentional human dosing and the principles of the Nuremberg Code with respect to human experimentation.” The EPA finalized the rule under these provisions stating, “EPA will neither conduct nor support any intentional dosing studies that

involve pregnant or nursing women or children for all substances EPA regulates." The Federal "Common Rule" created requirements for the protection of human subjects from experiments done by the EPA and the USDA." http://www.ens-newswire.com/ens/jan2006/2006-01-25-05.asp.

The list of evidence given thus far is to help the reader be absolutely clear, that the aerial application of Checkmate, on humans, is a pesticide experiment. This is certain because, Checkmate has never been tested, on agriculture, or humans. Every type of LBAM management technology, sticky traps, twist ties, and ground spray, is only designed for agriculture. Even using those proven technologies on populated areas, would constitute, an experiment, as the side-effects and efficacy, are unknown.

Part of Nuremberg Code, Directives for Human Experimentation

1. The voluntary consent of the human subject is absolutely essential.
2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
4. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
5. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
6. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

Full Code At: http://ohsr.od.nih.gov/guidelines/nuremberg.html

The aerial application of Checkmate is not just a pesticide experiment, but under State and Federal laws, a medical experiment. One intent of State and Federal Health and Safety laws, is to protect the Nuremberg Code of Ethics in Medical Research, in order to prevent unethical conduct. The CDFA, EPA, and USDA will argue that they are not doing any medical experiments, yet the application of a biochemical that has never even been tested, not even on moths in a field, being tested on humans, is by definition, and fact, an experiment on humans. Checkmate aerial applications fall under the legal definition of a human experiment under the California Health and Safety Code (CH&S) section 24170-24179.5. (Parts of Code Are Attached) This code defines a medical experiment to include a "biological substance or organism" that can penetrate or damage

human tissues. In the case of the Checkmate formulations, the pheromone is a biological substance and organism. Bacillus thuringiensis (Bt) is a gram-positive, soil dwelling bacterium of the genus Bacillus.

Normally the use of the pheromone is not a medical experiment because it is applied to plants in agricultural fields. Surely breathing in the pheromone, or breathing in a microscopic ball of plastic impregnated with pheromone is one instance of proof that Bt penetrates the human body and its tissues. The microencapsulated Checkmate, including its micro-flake mating disruption flake, sprayed on humans, also falls under the definition of a medical device. Medical devices include "in vitro reagent," a device outside of the body that takes part in a chemical reaction. The chemical reaction of Checkmate, is to slowly degrade over 30 to 70 days to release pheromone. Wet and dry conditions influence the chemical reactions in different ways.

Checkmate also falls under the legal definition of a drug, under California State Law, and likely under the Federal Food, Drug, and Cosmetic Act [See Section 201(g)(1)].. California State law says that a drug is "Any article other than food, that is used or intended to affect the structure or any function of the body of human beings or any other animal." (CH&S section 109925(C)) Yet, the Section 18 emergency gives the EPA and the CDFA the right to overlook many concerns in the name of defending our agriculture by using a preemptive strike tactic to eradicate the enemy moth.

The use of Checkmate clearly affects the function of the human body. This is undeniable because microcapsules can either stick onto people's skin causing a chemical reaction, or, be inhaled into people's nose or mouth, as well as enter the mucous membranes of the eye. Minute plastics laced with extremely toxic chemicals, along with pheromones, within people's bodies and blood will and must affect the bodily function in some way as the body must respond and react to the presence of these synthetic substances.

In addition, the presence of the hormone mimicking 2-hydroxy-4-n-octyloxybenzophenone is one indication of the intention of Checkmate to be a drug, as well as reasonable proof that Checkmate will cause serious effects. The undeniable and immediate physiological reactions happening to large numbers of citizens in the spray zones, confirm the facts that Checkmate, and its related chemical applicators, act like drugs in humans. This is clear and convincing evidence that in addition to the violation of spraying pesticides on people, that Checkmate acts like a drug, and is thus subject to medical experimentation laws. Since approximately 100,000 citizens did not consent to being experimented upon, this is an extreme violation of the Nuremberg Code, which was made into law by State and Federal Statues.

To this day, Monterey County citizens have been told by Senator Boxer and Feinstein's offices, as well as Congressman Farr's office that this issue is under the jurisdiction of the State of California, even though the project remains funded by the USDA via the Department of Homeland Security. The only legislator who has come forward and demanded more information be gathered, testing be done and a delay in spraying to take place is Assemblyman John Laird. He has spoken out in repeated letters to Sec. Kawamura asking for more research and for a protocol to be assembled to handle health concerns. At this point, many

citizens feel a sense of hopelessness due to the lack of action taken by their local governments, the failure of the courts and the apparent disregard of human suffering and consequence shown by the CDFA, EPA and USDA.

Human and pesticide experimentation is not just a possible horrible event for the future; it has happened twice already and will continue to happen, again and again. Spraying is set to begin on November 4th 2007 in Santa Cruz, CA for six nights. The city council of Santa Cruz and the Board of Supervisors has voted to seek legal action and will likely seek a Temporary Restraining Order to halt spraying. Local citizens are also pursuing their own legal case should their city council fail.

In summary, the situation in Monterey County California is serious and cause for deep alarm because:

#1 This is a "false emergency": in Australia and Hawaii, the LBAM is hardly a concern and definitely does not threaten their agricultural commodities. In addition,, the LBAM likes cold climates, which means it physically cannot survive in the various agricultural districts in the warmer climates of California that the CDFA claims it is protecting through LBAM eradication.

#2 There is no evidence to support that Checkmate is safe or effective because it has never been tested and because even ground based pheromone applications never eliminate populations but rather control populations.

#3 People have never been directly and purposefully targeted and sprayed with an untested pesticide, which is violating, California State, EPA and Congressional Guidelines against human testing.

#4 The targeting of cities is capricious and arbitrary because it does not establish a complete buffer zone around moth finds.

#5 Areas that do not have high concentrations of moth findings were sprayed first, showing the CDFA is not that interested in eradicating the LBAM at the most infested points. In addition, the highest concentration of LBAM is not in Monterey or Santa Cruz Counties, but in San Francisco.

#6 The funding for this "eradication" program comes from the Department of Homeland Security.

#7 Testing a microencapsulated biological agent on infants, children and pregnant women, against their will, is an obvious and blatant violation of human rights under the Nuremberg Code.

#8 Blatant misrepresentation of the environmental harm by the CDFA, the EPA, and the USDA has taken place as this pesticide was deemed safe by the CDFA Advisory Council repeatedly at town hall meetings. It is also known that microcapsules can cause avian deaths, and cause bees to mistake the capsules for pollen.

#9 The potentially deadly side effects of spraying Checkmate products are already emerging from aerial applications as citizens report widespread health effects.

#10 Most local governments, doctors, legislators and environmental groups are either reluctant or refuse to take action over this issue for fear of being unable to prove the CDFA wrong even though the CDFA has not proven their

method is tested, safe or effective. Fear of being sued is keeping local governments from protecting their own citizens.

Local community organizations are taking the responsibility for human health into their own hands by working to compile citizen health reports on their own as they continue to work with health practitioners, scientists and environmental groups to document the relationship between the chemicals being sprayed and the reported effects. Legal action seems to be the only hope in stopping this assault on the Central Coast of California. If legal action is successful in Santa Cruz County, the CDFA may have to abandon their master eradication plan to spray the entire Bay Area, including areas of San Jose, San Francisco and Marin Counties.

Supporting Evidence

List of Published checkmate Ingredients, October 20, 2007, CDFA Press Release (Other ingredients are trade secrets and are unknown)
(E)-11-Tetradecen-1-yl Acetate
(E,E) -9,11 Tetradecadien-1-yl Acetate
Crosslinked polyurea polymer
Butylated Hydroxytoluene
Polyvinyl Alcohol
Tricaprylyl Methyl Ammonium Chloride
Sodium Phosphate
Ammonium Phosphate
1,2-benzisothiozoli-3-one
2-hydroxy-4-n-octyloxybenzophenone
http://www.cdfa.ca.gov/egov/Press_Releases/Press_Release.asp?PRnum=07-086

Acknowledgement of Human Testing by EPA with LBAM - EPA justifies testing saying human effects are negligible.

EPA Quarantine Exemptions for Light Brown Apple Moth Pheromones

6. Residential and by-stander exposure is expected to be low due to the low application rate and the specific methods of application. EPA believes use of these pheromone products, including aerial application over residential areas, presents negligible risks to human health and the environment. Furthermore, there are no restrictions for re-entering treated residential or recreational areas**.**

8. EPA carefully evaluated the safety of the requested quarantine uses of these pheromone products and supports their use, and as noted previously, believes the risks to human health and the environment are negligible.
http://www.epa.gov/pesticides/local/region9/lbam_quarantine.htm

Laws Violated

Common Rule. The Federal Government has established common requirements for the protection of human subjects involved in research conducted or funded by a number of Federal Departments and Agencies including EPA and United States Department of Agriculture (USDA) (U.S. EPA, 1991). These requirements are known informally as "the common rule."

http://www.epa.gov/scipoly/sap/meetings/1998/march/part-a.pdf

Text of Described Moratorium by Congress: H.R.2361 Department of the Interior, Environment, and Related Agencies Appropriations Act, 2006

Administrator of the Environmental Protection Agency to accept, consider or rely on third-party intentional dosing human toxicity studies for pesticides, or to conduct intentional dosing human toxicity studies for pesticides until the Administrator issues a final rulemaking on this subject.

Such rule shall not permit the use of pregnant women, infants or children as subjects; shall be consistent with the principles proposed in the 2004 report of the National Academy of Sciences on intentional human dosing and the principles of the Nuremberg Code with respect to human experimentation.

EPA Policy That Resulted From Moratorium. Expanded Protections for Subjects in Human Studies Research

EPA will neither conduct nor support any intentional dosing studies that involve pregnant or nursing women or children for all substances EPA regulates. EPA is also extending new ethical protections to adult (non-pregnant, non-nursing) subjects involved in intentional dosing human studies for pesticides.

http://www.epa.gov/oppfead1/guidance/human-test.htm

Summary of California Health and Safety Code:

The legislature believes human experimentation without informed consent is unethical; and describes a need to protect citizens from such experiments. The definition of medical experiment includes “biological substance or organism” that can penetrate or damage human tissues. A medical device is defined as a device that can affect any function of the body of humans or any other animal. Medical devices include “in vitro reagent” a device outside of the body that takes part in a chemical reaction. A drug is any substance except food that affects the structure of function of the human body. A person who fails to obtain the subjects informed consent and exposes subject to unknown but serious injury, shall be punishable by imprisonment in the county jail for a period not to exceed one year or a fine of fifty thousand dollars ($50,000), or both. Each and every medical experiment performed in violation of any provision of this chapter is a separate and actionable offense.

CALIFORNIA CODES
HEALTH AND SAFETY CODE
SECTION 24170-24179.5

24171. The Legislature hereby finds and declares that medical experimentation on human subjects is vital for the benefit of mankind, however such experimentation shall be undertaken with due respect to the preciousness of human life and the right of individuals to determine what is done to their own bodies.

The Legislature further finds and declares that:

(a) The Nuremberg Code of Ethics in Medical Research was developed after the trial of Nazi war criminals for unethical use of persons in medical experiments; subsequently, the Declaration of Helsinki additionally established recommendations guiding doctors in experimentation involving human subjects.

(b) Neither the Nuremberg Code nor the Declaration of Helsinki are codified under law and are, therefore, unenforceable.

(c) It is necessary that medical experimentation be done in such a way as to protect the rights of the human subjects involved.

(d) There is, and will continue to be, a growing need for

protection for citizens of the state from unauthorized, needless, hazardous, or negligently performed medical experiments on human beings.

It is, therefore, the intent of the Legislature, in the enacting of this chapter, to provide minimum statutory protection for the citizens of this state with regard to human experimentation and to provide penalties for those who violate such provisions.

24172.

(j) Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

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24174. As used in this chapter, "medical experiment" means:

(a) The severance or penetration or damaging of tissues of a human subject or the use of a drug or device, as defined in Section 109920 or 109925, electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human subject in the practice or research of medicine in a manner not reasonably related to maintaining or improving the health of the subject or otherwise directly benefiting the subject.

(b) The investigational use of a drug or device as provided in Sections 111590 and 111595.

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Medical Device

(c) Intended to affect the structure or any function of the body of humans or any other animal and that does not achieve any of its principal intended purposes through chemical action within or on the body of humans or other animals and that is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

109920. "Device" means any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, that is any of the following:

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109925. "Drug" means any of the following:

(c) Any article other than food, that is used or intended to affect the structure or any function of the body of human beings or any other animal.

24170. This chapter shall be known and may be cited as the Protection of Human Subjects in Medical Experimentation Act.

24175. (a) Except as otherwise provided in this section, no person

shall be subjected to any medical experiment unless the informed consent of such person is obtained.
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(c) Any person who is primarily responsible for the conduct of a medical experiment and who willfully fails to obtain the subject's informed consent, as provided in this chapter, and thereby exposes a subject to a known substantial risk of serious injury, either bodily harm or psychological harm, shall be guilty of a misdemeanor punishable by imprisonment in the county jail for a period not to exceed one year or a fine of fifty thousand dollars ($50,000), or both.

(d) Any representative or employee of a pharmaceutical company, who is directly responsible for contracting with another person for the conduct of a medical experiment, and who has knowledge of risks or hazards with respect to the experiment, and who willfully withholds information of the risks and hazards from the person contracting for the conduct of the medical experiment, and thereby exposes a subject to substantial risk of serious injury, either bodily harm or psychological harm, shall be guilty of a misdemeanor punishable by imprisonment in the county jail for a period not to exceed one year or a fine of fifty thousand dollars ($50,000), or both.

(e) Each and every medical experiment performed in violation of any provision of this chapter is a separate and actionable offense.

(f) Any attempted or purported waiver of the rights guaranteed, or requirements prescribed by this chapter, whether by a subject or by a subject's conservator or guardian, or other representative, as specified in Section 24175, is void.

(g) Nothing in this section shall be construed to limit or expand the right of an injured subject to recover damages under any other applicable law.

http://www.leginfo.ca.gov/cgi-bin/waisgate?WAISdocID=7119538493+0+0+0&WAISaction=retrieve

Federal Food Drug and Cosmetic Act, Sec. 201
(g)(1) The term "drug" means (A) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 403(r)(1)(B) and 403(r)(3) or sections 403(r)(1)(B) and 403(r)(5)(D), is made in accordance with the requirements of section 403(r) is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 403(r)(6) is not a drug under clause (C) solely because the label or the labeling contains such a statement.