



ALLIANCE FOR HUMAN RESEARCH PROTECTION

FDA Safeguards Undermined by a Bad Judicial Ruling, a Bioethics Smokescreen, and a Trojan Horse

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Federal safeguards to protect public health and safety are being swept aside to accommodate corporate interests.

Game changer: a Federal court decision undercuts FDA's authority to prohibit manufacturers from promoting prescription drugs with unsubstantiated marketing claims. This decision may open the floodgates for indiscriminate commercial promotion of hazardous prescription drugs for unapproved, unsafe uses in contradiction to the Food, Drug and Cosmetics Act.

Trojan Horse: A series of "emergency preparedness" laws have been rushed through Congress, empowering the Secretary of Health and Human Services (HHS) with discretionary authority to declare health emergencies—without specifying any criteria for what constitutes a health emergency; and to declare selected vaccines and drugs as "medical countermeasures" that are exempted from FDA safety or efficacy requirements.

HHS Assistant Secretary for Preparedness and Response (ASPR, created in 2005), is the authorized leader for coordinating emergency preparedness planning, prevention and response programs; advancing research and development of "medical countermeasures"; procuring for the civilian stockpile; and distributing for use of "medical countermeasures" such as vaccines, whose safety and efficacy may not have been established in humans.



A PREP Act Emergency Declaration grants extraordinary immunity from all legal liability to manufacturers of medical countermeasures, healthcare professionals who dispense them and government officials who set countermeasure policy.

But citizens who may be harmed by defective vaccines and drugs declared to be medical countermeasures, are deprived of their right to judicial due process and compensation.

1. **Game Changer:** on December 3, 2012, in a two to one decision, [United States v Caronia](#), the US Court of Appeals for the Second Circuit (New York) overturned the conviction of a pharmaceutical

company sales representative (Alfred Caronia) who was convicted by a jury (in 2008) for conspiring “to introduce a misbranded drug into interstate commerce,” in violation of the Food, Drug and Cosmetics Act. Caronia and Peter Gleason, MD, a paid consultant, promoted the expansive use of the drug, Xyrem (manufactured by Jazz Pharmaceuticals), for a wide range of unapproved, off-label uses. Such illegal promotion of prescription drugs by manufacturers and their agents has heretofore led to numerous government prosecutions resulting in increasingly costly multi-billion dollar settlements.

Indeed, in 2007, [Jazz Pharmaceuticals pled guilty](#) and resolved a criminal suit by the US State Attorney for the Eastern District (NY); it settled for \$20 million. In 2011, [GlaxoSmithKline](#) pled guilty to criminal charges for promoting Paxil, Wellbutrin, and Avandia for unapproved uses and failing to report safety data, settling for \$3 billion. In 2013, a federal appeals court upheld a verdict ordering [Pfizer](#) to pay \$142 million for marketing Neurontin for unapproved uses. See: [Pharma’s Rap Sheet](#).

Xyrem (γ-Hydroxybutyric acid (GHB)) is a powerful, fast-acting central nervous system depressant that has been used as a general anesthetic. Because it is subject to abuse as a “Date Rape Drug” surreptitiously used to facilitate sexual assault, it is highly controversial. In many countries GHB is an illegal drug. The FDA approved Xyrem in 2002 for restricted use for patients with narcolepsy. It is classified as a Schedule III controlled substance.

Because of the severe side-effects—including **seizures, respiratory depression and profound decreases in level of consciousness, with instances of coma and death**—and its abuse potential, the FDA required a “[Black Box](#)” label warning, and limited its nationwide distribution to a single pharmacy. Even at recommended doses, Xyrem’s use has been associated with confusion, depression and other neuropsychiatric events. **Additional Warning:** *“The rapid onset of sedation, coupled with the amnestic features of sodium oxybate, particularly when combined with alcohol, has proven to be dangerous for the voluntary and involuntary (assault victim) user.”*

At trial, the government produced taped evidence demonstrating that Mr. Caronia had promoted Xyrem to doctors for treating insomnia, Fibromyalgia and restless-leg syndrome. Furthermore, in contradiction to the label warning: “Xyrem has not been tested for use in children under 16,” he promoted its use for children “as young as fourteen” claiming **“it’s a very safe drug.”**



Dr. Gleason, a psychiatrist who was paid to promote Xyrem for [unapproved uses](#), told doctors that Xyrem was “[safer than table salt](#)” and “[safe for children.](#)” He was arrested in New York, pled guilty and was convicted with Caronia for “misbranding.” His medical license was suspended in Maryland, Pennsylvania, and California. He moved to Florida, pled guilty to a misdemeanor, and was sentenced to one year probation; but Dr. Gleason [committed suicide](#).

[A pattern of public safety violations:](#) in 2011, “the FDA inspected Jazz facilities and discovered that the drugmaker had failed to report 74 serious and unexpected adverse events, including 10 patient deaths, concerning its Xyrem medication that is used to treat muscle weakness in people with sleep disorders. FDA regulations require that such reports to be filed within 15 days of initial receipt.”

The Court of Appeal decision by two federal judges—Denny Chin (appointed by President Obama, 2010) and Reena Raggi (appointed by President Bush, 2002) ruled that commercial sales pitches are protected under the First Amendment—even though the intent of those unsubstantiated promotional claims was to expand the use of an exceedingly dangerous drug whose use was restricted by FDA.



The decision undercuts the very foundation of drug regulation safeguards as set forth under the Food, Drug and Cosmetics Act (FDCA) requiring manufacturers to prove safety and efficacy BEFORE they can promote a use.

Judge Denny Chin, who wrote the decision, argued that the FDA discriminates unfairly by criminalizing manufacturers' sales reps for promoting products for unproven, off label uses whereas doctors are free to do so.

The intent of the First Amendment was to ensure the free exchange of ideas. By applying constitutional protections for individual free speech—to commercial speech promoting hazardous drugs whose use is restricted by law—these judges sacrificed public safety in support of commerce. They turned a blind eye to the harmful consequences expanded use of this dangerous drug will have.

The ruling compounds injury to public safety by eliminating the off-label promotion prohibition entirely—even as it applies to an exceedingly dangerous drug with a history of abuse and deaths. The court might have suggested that the prohibition against unsubstantiated, off-label promotion should apply as well to doctors who are paid to promote prescription drugs for unapproved, unsubstantiated, potentially hazardous uses.

In her thoughtful, vigorous dissenting opinion, Judge Debra Ann Livingston wrote:



“the majority calls into question the very foundations of our century-old system of drug regulation... If drug manufacturers were allowed to promote FDA-approved drugs for non-approved uses, they would have little incentive to seek FDA approval for those uses... Prohibiting such promotion is thus one of the few mechanisms available to encourage participation in the approval process... And premarket approval improves drug safety and effectiveness only to the extent that drugs are not sold without such approval.”

“But if drug manufacturers have a First Amendment right to distribute drugs for any use to physicians or even directly to patients, then the entire FDCA may well be unconstitutional.”

This decision as well the Supreme Court decision, [Sorrell v. IMS Health](#) (June 23, 2011), overturning a Vermont law restricting the use of prescription data for marketing purposes, demonstrates that even members of the judiciary have been swept up by a culture that values corporate commercial interests above public safety.

2. Using “Bioethics” to Subvert Statutory Protections for Children

Between 2001 and 2009 the US spent more than \$50 billion for accelerated development and procurement of therapeutic countermeasures against biological warfare threats; biodefense contractors have been cashing in on non-competitive US government contracts for medical countermeasures. For example, the Public Readiness and Emergency Preparedness Act (PREP Act, 2005), was secretly tagged on to the Department of Defense appropriations bill **“for the purpose of providing immunity from legal liability to manufacturers of any vaccine or drug”** that the Secretary of HHS designates to be a *“medical countermeasure.”*

On October 1, 2008, then HHS Secretary Michael Leavitt declared an [anthrax emergency](#) to be in effect through December 31, 2015—despite the written disclaimer by Homeland Security Secretary Michael Chertoff stating that there was [no evidence of anthrax](#) risk to support the declaration.

The primary beneficiary of the “anthrax emergency declaration” has been the vaccine’s manufacturer, Emergent BioSolutions (a.k.a. BioPort) which was provided an [iron-clad shield](#) from legal liability for any harm:

“Immunity from tort liability means there is no legal tort claim that can be pursued in court [...] under Federal or State law for any type of loss including death; ... with any causal relationship to any stage of development, distribution, administration or use of the covered countermeasure recommended in the declaration.”

Emergent BioSolutions has been especially successful at garnering ever expanding government contracts for the civilian stockpile at extraordinarily lucrative margins—in this case, a 300% profit margin. The magnitude of its profit margins led the [Center for American Progress](#) (2010) to question the integrity of the government procurement system. See also, a probing article about [Bioterrorism Preparedness](#) by Wil Hylton in the *New York Times Magazine*, 2011.



Emergent is proud to play a significant role in the U.S. government’s biodefense strategy to help keep the nation safe.

Emergent has entered into a partnership with the Biomedical Advanced Research and Development Authority (BARDA) within the U.S. Department of Health and Human Services (HHS) to establish a Center for Innovation in Advanced Development and Manufacturing. The Center will facilitate advanced development of medical countermeasures for combating threats to national security and public health.

“Emergent is pleased to enter into this long-term public-private partnership with BARDA to help achieve our common goal of strengthening national security and preparedness efforts,” said Daniel J. Abdun-Nabi, President and Chief executive Officer.

Video: HHS press conference (25:00)

Emergent press release

HHS press release



Left to right: HHS Secretary Sebelius; Fouad El-Hibri, Founder, Emergent; Andrin Oswald, President Novartis; Nicole Lurie, Assistant Secretary; Brett Giroir Vice Chancellor, Strategic Initiatives, Texas A & M

The Centers for Disease Control (CDC) does not recommend vaccination against anthrax for anyone who is not at high risk—such as persons who work directly with the bacteria in a laboratory.

Children are not at risk of anthrax; if ever children (or adults) were exposed to anthrax spores, they would be given [antibiotics](#), such as Ciprofloxacin or Doxycycline, which have been FDA-approved for pediatric use against anthrax—and recommended by CDC.

Anthrax vaccine poses serious risks of harm and its efficacy following exposure to inhaled anthrax remains in doubt. Indeed, *BioThrax* (AVA) is not licensed for use following anthrax exposure because evidence of the vaccine’s efficacy following exposure to anthrax spores has not met FDA standards. The 2012 [vaccine label](#) warns:

“The safety and efficacy of BioThrax in a post-exposure setting have not been established.”

Furthermore, “acute allergic reactions, including anaphylaxis...Stevens Johnson syndrome have occurred with BioThrax... [and] BioThrax can cause fetal harm when administered to a pregnant woman. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus...”

Read the [AHRP Report](#) including copious citations to government documents analyzing anthrax vaccine safety and efficacy data; [highlights here](#).

Children lack legal capacity to consent to assume research risks; Federal statutes explicitly prohibit exposing children to research involving more than “a minor increase over minimal risk” with no prospect of a direct benefit, unless:

*“The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is **of vital importance** for the understanding or amelioration of the subjects' disorder or condition” [45 CFR Sec. 46.406]*

“...the research presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.” [Sec. 46.407]

Despite Federal statutory prohibitions, HHS Secretary, Kathleen Sebelius, and Assistant Secretary for Preparedness and Response (ASPR), Nicole Lurie, MD, have been aggressively campaigning to test the controversial anthrax vaccine and more broadly, “medical countermeasures” that may be used in the event of a chemical, biological, radiological or nuclear attack— in children.

The proposed experiment fails to meet these ethical and legal criteria for approval inasmuch as healthy children with no “disorder or condition” would be sought as test subjects, and anthrax does not pose “a serious problem affecting children.” Contrary to assurances that “the safety of our children is paramount,” countermeasure research would undermine children’s safety by exposing them to undue risk of harm in violation of Federal law. Absent an imminent threat, the proposed experiment in children would violate bedrock medical ethics principles: the Hippocratic Oath—“Do No

Harm,” the Nuremberg Code, and Federal statutory protections. Furthermore, risks for children in medical countermeasure research are compounded by the PREP Act and its sweeping indemnification from all liability. A child who may be injured in countermeasure research is barred from seeking compensation through any state or federal judicial court.

Why are children in the crosshairs of HHS’ anthrax vaccine policy?

Children make up 25% of the US population; they are legally incapable of giving or withholding informed consent to medical research. An anthrax vaccine experiment offers no prospect of a direct benefit to the children who would be exposed to serious risk of harm and they would suffer significant pain—as documented in a [GAO survey](#) of military personnel. But testing the vaccine in children could be used by HHS officials to justify expanding the civilian stockpile. But inasmuch as Federal protections restrict use of children in research not in their best interest that pose greater than minimal risk, Secretary Seblius and ASPR Secretary Lurie have embarked on a concerted effort aimed at [circumventing \(overriding\) Federal statutory research restrictions](#).

Federal statute provides a [legally mandated](#) (45 CFR 46.407) **publicly open national level review** to determine whether specific circumstances exist such that the magnitude of danger for children may transcend the statutory restrictions on exposure of healthy children to more than “*a minor increase over minimal risk*” in research. This [safeguard](#) “*provides a national perspective to the ethical evaluation and approvability of research involving children.*” But **lacking any evidence of a real threat for children**, Secretary Sebelius and Assistant Secretary Lurie, are loath to submit a pediatric anthrax vaccine protocol for evaluation and public scrutiny under 45 CFR 46.407.

Instead, they have sought endorsement for an ethically and legally unapprovable experiment from two HHS-subsidized advisory commissions—one appointed by President Obama, the other by Dr. Lurie. To justify testing anthrax vaccine in children, they invoked a fictional scenario of a simulated anthrax attack—a war game named “Dark Zephyr”—rather than any real threat required under 407.

In October 2011, the [National Biodefense Science Board](#) endorsed the proposed anthrax vaccine experiment while explicitly acknowledging that “**administering AVA to children would present more than a minor increase over minimal risk**” with no direct benefit to the children. Its endorsement was contingent on the proposal being reviewed by a panel of ethicists. HHS Secretary Sebelius submitted the request to the Presidential Commission for the Study of Bioethical Issues (Bioethics Commission).

On March 19, 2013, the Bioethics Commission issued its [Report and Recommendations](#), preceded by a [Press Release](#) and Press teleconference at which the Commission chair, Dr. Amy Gutmann, took great pains to cloak the Commission’s proposals in righteous window-dressing, echoing Secretary Sebelius’ charge to the Commission:

“The safety of our children is paramount and we have to get this precisely right... significant steps would have to be taken, including additional minimal-risk research with adult volunteers, before pediatric anthrax vaccine trials prior to an attack should be considered... our nation must protect children enrolled in research studies while also doing its best to develop the knowledge needed to save children’s lives during a possible emergency.”

The Bioethics Commission affirmed existing ethical statutory restrictions protecting children from unjustifiable research risks by stating that absent an event posing a threat for children:

“pediatric MCM [medical countermeasure] research —which presents no prospect of direct benefit because no children are affected by the condition being studied—generally cannot proceed unless it is minimal risk research.”

But the Commission obliged HHS by recommending an alternate strategy that they call, “**age de-escalation**,” a clever **linguistic ruse** suggesting a reasoned, deliberative means for reducing risk.

Age de-escalation is a smokescreen misrepresented as a strategy “to minimize risk to children.” In reality, the Commission paved the way for the anthrax vaccine experiment to proceed by asserting that risk for children can be reduced to “minimal risk” through age de-escalation.



Amy Gutmann, PhD. Chair
Bioethics Commission
President U. Pennsylvania

“Pre-event research might in some cases be designed in a way that would permit it to be judged minimal risk through an age de-escalation process in which risks are assessed and evaluated at each step. Robust research with young adults might support the conclusion that research with the oldest children is minimal risk.

Similarly, research with the oldest children that further characterizes research risk might support an inference that research with the next oldest group of children is minimal risk as well...Informed, careful age de-escalation might allow researchers to infer minimal risk studies down the age scale.”

[Presidential Commission Report, 2013](#)

But age de-escalation cannot eradicate the extensive body of clinical evidence documenting anthrax vaccine’s serious risks of harm in adults—nor can this formula prevent vaccine-induced birth defects—a serious risk for young adults and teens who may become pregnant.



In CDC’s pivotal study there were 14 pregnancies in the first trimester—the most dangerous period: of these 2 ended in spontaneous abortions, 1 fetal death in utero, and 1 infant with clubbed foot.

The Commission’s age de-escalation formula designates older teenagers as the first to be exposed to the vaccine.



The inherent serious risks posed by countermeasure products cannot be mitigated or avoided by age de-escalation.

A case of obfuscation: the Commissioners failed to acknowledge evidence of anthrax vaccine’s known serious risks, and unsubstantiated claims about the vaccine’s “life-saving” effectiveness following exposure; instead they concocted “age de-escalation,” pretending it was a safety strategy and that it may reduce the vaccine’s risk to “minimal risk.”

The Commission:

- misrepresented the vaccine as posing only “*minimal risk in adults*”
- misrepresented “*immunogenicity*” (the ability to induce antibodies) as evidence of “*efficacy*” (the ability to prevent disease and death) which has never been demonstrated in humans
- succeeded in [confusing the media](#).

Indeed, some media reports stated that the Commission nixed anthrax vaccine tests in children, while others reported that the Commission gave a tentative green light for the experiment to proceed.

Not only does the Commission’s report fail to consider—or even acknowledge—an existing body of evidence from decades of adult trials and military experience documenting the vaccine’s serious safety hazards—including warnings in the FDA-vetted label—the report is littered with patently false statements. For example,

“its safety is comparable to other vaccines regularly administered during routine medical appointments... Accordingly, it might be possible to conclude that the administration of AVA in adults is minimal risk.” P.71-72

The Commission’s safety claims are contradicted in government reports documenting the vaccine’s serious risks: [FDA](#), [GAO](#), [CDC](#)



In 2007, the Government Accountability Office ([GAO](#)) [reported to Congress](#):

“Officials at the Military Vaccine Healthcare Centers Network and CDC estimate that between 1% and 2% of vaccinated individuals “may experience severe adverse events, which could result in disability or death.”

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In 2008, partial safety findings from CDC’s “pivotal safety / immunogenicity trial” conducted at the request of Congress were reported in [JAMA](#): **12% of the subjects in this “pivotal trial”—186 people suffered 229 “serious adverse events” during the trial with 7 deaths:**

*“The following AEs were classified as serious (SAE), consistent with US regulations: **death, life-threatening event, initial inpatient hospitalization or prolongation of hospitalization, significant or persistent disability or incapacity, congenital anomaly or birth defect, and a medical event that required medical or surgical intervention to prevent one of the other outcomes.”** Marano, et al, [JAMA](#), 2008*

A 2010 CDC review of [FDA’s Vaccine Adverse Event Reports](#) (VAERS) found 6,015 reports of which 600 (9.9%) “were categorized as serious events (i.e., events resulting in death, hospitalization, or permanent disability).”

Compounding the safety problems is lack of evidence for the vaccine’s efficacy:

Decades of immunogenicity trials in adults have failed to produce acceptable data to convince the FDA of the vaccine’s efficacy following exposure to anthrax. This is due to failure to establish a valid animal model of survival data from vaccinated experimental animals exposed to anthrax spores.

“For many of the threat agents—anthrax, smallpox, and plague— animal models that simulate critical features of the human disease or condition have not been developed.” [FDA](#), 2012

Lacking an appropriate animal model, scientists are unable to extrapolate the vaccine’s efficacy from animals to humans—which is the reason FDA has not licensed the vaccine for this purpose. As recently as January 28, 2013, the vaccine manufacturers’ scientists acknowledged in a [published report](#) that an animal model for demonstrating the efficacy of *BioThrax* in humans is still lacking.



“Animal models of diseases that afflict humans are critical tools for developing medical countermeasures against life-threatening conditions, such as inhalational anthrax, for which clinical evaluation of efficacy is not feasible.... well-established models do not respond to a specific countermeasure in a manner consistent with human response and, therefore, cannot be utilized for the assessment of efficacy of such countermeasures.”

Savransky, et al. Inhalation Anthrax in Guinea Pig Model, [American Society of Microbiology](#)

If decades of trials in animals and adults have failed to provide acceptable evidence of the vaccine's efficacy in humans, a pediatric trial cannot possibly provide any clinically or scientifically useful efficacy information either. Federal statute prohibits conducting research with adults without evidence of "the importance of the knowledge gained or to be gained," much less with children. [45 CFR 46.120]

If children were ever exposed to anthrax spores, they would receive [antibiotics](#) which were [proven 100% effective](#) in preventing anthrax in people who were treated after exposure to anthrax-laced letters in 2001. How then, did the Commission justify subjecting children to the serious long-term risks, or even to the temporary but significant pain and malaise?

This Bioethics Commission includes two university presidents, professors of law, ethics, medicine, and philosophy; its staff of 18 includes 6 PhDs and 6 lawyers. However, the *modus operandi* of these high ranking academics was shaped by a **strategy of deliberate ignorance**. They disregarded a body of evidence in the scientific literature; failed to invite testimony from a single anthrax vaccine expert scientist; and used propaganda to airbrush the vaccine's hazards and unproven efficacy.



"Facts do not cease to exist because they are ignored."

Aldous Huxley, *Proper Studies*, 1927

This Commission violated standards of [intellectual honesty](#) by purposely omitting facts / information:

- **disregarded** an existing body of anthrax vaccine literature ;
- **turned a blind eye** to the vaccine's serious **safety hazards in adults**—including **birth defects**;
- **purposely omitted** mention of FDA mandated safety warnings in the label;
- **misrepresented** the vaccine as "minimal risk" in adults;
- **conflated** immunogenicity with efficacy

Instead of an honest academic evaluation of the evidence, this Bioethics Commission crafted a formula for [illegitimately redefining](#) hazardous medical countermeasures research as "minimal risk." Its **de-escalation** recommendation is a **smokescreen** providing HHS officials—whose objective is to circumvent federal restrictions protecting children from unjustifiable research risks—with a **strategy for avoiding an open public review** of each specific protocol, as mandated under 45 CFR 46.407. This Commission of academics provided a spurious "ethical seal" to countermeasure research which will expose children—not their own—to significant risks, not to mention pain, with no benefit for them. **Age de-escalation cannot and will not eliminate the inherent serious risks of the anthrax vaccine.**

The Presidential Commission's Recommendations may have been rendered legally moot by the [Pandemic and All-Hazards Preparedness Reauthorization Act of 2013](#).



PAHPRA: A Statutory Trojan Horse

This law (signed March 13, 2013) casts aside FDA safety standards and side-steps children's statutory protections from risk in non-therapeutic medical experiments.

Sec. 302 *Revises HHS Secretary's authority to allow the use of unapproved medical products or the unapproved use of an approved product.*

- *Authorizes the Secretary to make a declaration that the circumstances exist justifying such an authorization and base the determination on:
(1) a (general) threat (rather than a specific threat as under current law), (2) a significant potential for a public health emergency, (3) the health and security of U.S. citizens abroad, and (4) the identification of a material threat sufficient to affect national security. Eliminates the one-year expiration date for such an authorization (thus allowing it to continue).*
- *Authorizes the Secretary to determine that a laboratory examination or procedure associated with a medical device subject to an authorization is deemed to be in a particular category of examinations and procedures if such categorization would be beneficial to protecting the public health and the benefits of the categorization outweigh the risks.*
- *Authorizes the Secretary to extend the expiration date of eligible medical countermeasures during an emergency if: (1) the extension is intended to support the U.S. ability to protect the public health or military preparedness and effectiveness; and (2) the extension is supported by an appropriate scientific evaluation conducted or accepted by the Secretary.*
- *Authorizes the Secretary to permit deviations from good manufacturing practice requirements when the circumstances of a domestic, military, or public health emergency or material threat so warrant.*
- *Authorizes the Secretary to waive prescription requirements during an emergency and create and issue emergency use instructions to inform health care providers or individuals to whom an eligible product is to be administered concerning the product's approved, licensed, or cleared conditions.*
- *Authorizes the Secretary to waive requirements for a risk evaluation and mitigation strategy in the event of a domestic, military, or public health emergency (currently, such waiver authority applies only to a public health emergency) or the identification of a material threat sufficient to affect national security or the health and security of U.S. citizens abroad.*

Similarly, the authority of the Assistant Secretary of Preparedness is expanded under Section 102 and 307 which amends the Food Drug and Cosmetics Act, shifting FDA authority for testing and evaluating countermeasure products in children:

SEC. 307. PEDIATRIC MEDICAL COUNTERMEASURES.

“the Secretary shall solicit input from the Assistant Secretary for Preparedness and Response...

- *“for a drug that is a qualified countermeasure, a security countermeasure, or a qualified pandemic or epidemic product regarding the need for and regarding **the conduct of, pediatric studies under this section.**”*

The Secretary shall consider,

- *“therapeutic gaps in pediatrics that may include developmental pharmacology, pharmacogenetic determinants of drug response, metabolism of drugs and biologics in children, **and pediatric clinical trials;**”*
- *“Advice and Recommendations of the **Pediatric Advisory Committee Regarding Countermeasures for Pediatric Populations-***
- ***and the development of countermeasures for pediatric populations.**”*



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