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Who Decides What Drugs Are Forced on Children?

All children must be injected with dozens of vaccines before entering school or daycare, and some of these injections are given to infants within the first weeks or even hours of birth. Parents are led to believe that these injections are required. Who mandated these vaccines and what is the decision-making process?

Parents are excluded from the process of deciding what drugs are injected into their children's bodies. Most states allow a limited medical exemption and a religious exemption, and a few states allow a philosophical (or conscientiously held belief) exemption. But often great pressure is exerted on parents who try to use these exemptions, and about 98% of all children are vaccinated.

Since more vaccines are coming on the market every year and more are being mandated, it's time to ask and answer several questions about forced medical care of healthy children. (1) Do we want government to have the power to force medical treatment on children against their parents wishes? (2) Is the process that produces these mandates honest — scientifically, bureaucratically, legislatively, politically — and open to public scrutiny and peer review?

It's important to recognize that the government is using popular support for vaccines to subsidize states to set up vaccine registries to tag all children at birth and track their medical records all their lives, and the CDC is working to merge these registries into a national medical database. When completed, this will achieve one of the principal goals of the discredited Clinton health care plan: computerizing the health records of all Americans with unique personal identifiers (Social Security numbers, if possible).

Vaccine mandates go into effect in America in an intricate three-step procedure that evades accountability. *First*, the Food and Drug Administration (FDA) and its Vaccines and Related Biological Products Advisory Committee (VRBPAC) decide whether a vaccine can be licensed. *Second*, the Centers for Disease Control (CDC) and its Advisory Committee on Immunization Practices (ACIP) decide whether to include the vaccine on the Child Immunization Schedule, *i.e.*, put on the list of vaccines that are recommended to be given to all children. *Third*, state legislatures specify which vaccines and how many doses are required (or authorize a state health agency to put new vaccines on the compulsory list). State legislatures or agencies usually follow ACIP's recommendations.

It is obvious that the FDA/ACIP/state decisions make the approved vaccines immensely profitable by providing a guaranteed market. Federal laws are supposed to prohibit conflicts of interest, but commercial conflicts have emerged as a major concern.

Conflicts of Interest about Vaccines

When a rotavirus (infant diarrhea) vaccine was suddenly withdrawn from the market in 1999, the public was led to believe that it was because new information about harmful side effects had been discovered. At a June 15, 2000 hearing conducted by Rep. Dan Burton's (R-IN) House Committee on Government Reform, we learned that other factors influenced the 1998 FDA licensing and CDC recommendation.

Most of the work of the CDC advisory committee is done in "working groups" behind closed doors without public scrutiny. Six of the ten working groups had financial ties to pharmaceuticals that make rotavirus vaccines. It turns out that half of those on the two key committees voting for the rotavirus vaccine had financial ties to vaccine manufacturers, such as being paid as consultants or lobbyists or owning vaccine patents or owning stock in pharmaceuticals.

In pre-licensure trials for the rotavirus vaccine, some babies suffered obstructed bowels a week later, some requiring surgery to remove a portion of the intestine, a painful condition called intussusception. Nevertheless, the committees approved the vaccine for universal use, calling these reports statistically insignificant. The study data were concealed, and the public did not learn of the problem until more than 100 cases of intussusception were reported, including one death.

The vaccine was not even considered to be all that effective in preventing diarrhea in infants. In one U.S. multicenter trial, the rotavirus vaccine only had a 49% efficacy rate in preventing the rotavirus disease.

Within months after government approval, 1.5

million vaccine doses were given to infants. The Department of Health and Human Services, in its announcement, stated that "the most common adverse vaccine reactions included moderate fever, increased irritability, and decreased appetite and activity," with no mention of side effects requiring hospitalization or surgery.

The Burton hearings provided some answers to help explain this disaster. When the rotavirus vaccine was approved by the FDA committee, 8 members were absent, 2 were excluded, and 4 of the remaining 5 had conflicts of interest that necessitated waivers. This was not a quorum so they were joined by 5 temporary members, and then all voted to approve the vaccine. The committee's own charter states that temporary members are normally not to exceed 4.

The CDC routinely grants conflict-of-interest waivers to every member of its advisory committee a year at a time, and allows full participation in the discussions by all members even if they have a financial stake in the decision. One member who cast three votes to recommend the rotavirus vaccine owned a patent for another rotavirus vaccine and admitted that he was paid by the pharmaceutical industry to travel around the country and teach doctors that vaccines are safe.

The public still has no access to the actual data concerning side effects of the rotavirus vaccine or of the controversial chicken pox or hepatitis B vaccines. If these new vaccines are safe, there should be no objection to releasing the actual data that demonstrate this. The obvious incentive to conceal such data is to hide facts that discredit the public recommendations.

At Burton's June 15 hearing, officials from the FDA and CDC defended the various conflicts of interest because waivers were granted. One CDC official went so far as to suggest that it is good to use vaccine industry insiders on official advisory committees because they are able to vote based on secret drug-company information! That is tantamount to letting vaccine industry lobbyists write their own profitable government mandates, *i.e.*, simply own the process.

It is a great mistake to base vaccine policy on confidential or trade-secret data. Scientific claims are most reliable when all data and analyses are subject to public scrutiny. Our political system demands that government decisions be subject to democratic checks and balances.

The whole concept of the government forcing experimental treatment on healthy individuals is disturbing to those who value freedom. Mandatory vaccine policies depend on overwhelming public acceptance, but public confidence is eroded by conflicts of interest and secrecy of deliberations and data.

Government should put all the data, analyses and meeting minutes on a public website, and this should include a risk-benefit analysis, cost-benefit analysis, and a comparison against alternate policies. Only public data and arguments should be considered. The CDC should appoint advisory committee members with diverse points of view. Scientists from other fields, consumer advocates, and even vaccine critics would greatly improve the quality of the recommendations because more policy implications would be considered.

Who Imposes the Vaccine Mandates?

The December 27, 2000 issue of *JAMA (Journal of the American Medical Association)* contains a very important caveat about *who is responsible* for the decisions to mandate vaccines, even though the article supports the widespread policy of forcing all children to be vaccinated in order to enter daycare or school.

The *JAMA* article reports on a Centers for Disease Control (CDC) study that makes the unsurprising claim that unvaccinated children are more likely to get measles and pertussis than those who are vaccinated. The study used Colorado data because that is one of 15 states that allow parents a philosophical (conscientiously held belief) exemption in addition to the religious and medical exemptions. Only 1.4 percent claimed this exemption and more than 98% of Colorado children were vaccinated in the year cited by the study.

Vaccination is not effective in about 5 percent of children, so when there is a measles outbreak, most of the cases are among vaccinated children. The CDC has declared that the United States has been free from indigenous measles since 1998 and the only cases come in with immigrants.

For the Colorado study, the researchers had to go back more than ten years to find sufficient cases and include a measles epidemic. If the researchers wanted to discuss current risks accurately, they should have focused on immigrants and ineffective vaccinations rather than on children whom they disdainfully call "exemptors."

It appears that the "experts" and the "authorities" won't be happy until there is 100% compliance with vaccine mandates. The real purpose of the *JAMA* report seems to be to shame or scare the 1 to 2 percent of parents into *not* using a philosophical exemption and to induce states to repeal this exemption.

The same issue of *JAMA* includes an editorial commenting on this study. It, too, is based on the premise that vaccine mandates are desirable, and it deplores criticisms of vaccines by parents, implying that their objections must be based on ignorance or misinformation.

But buried in the *JAMA* editorial are some startling comments and revelations. *JAMA* absolves ACIP, CDC and FDA from any accountability for the *mandating* of vaccines in the three-step process described above. The editorial says, "It is *not* the responsibility of these advisory bodies to determine which vaccines are mandated; *that decision resides with the state*."

The *JAMA* editorial issues a warning to state legislators. They should not mandate a vaccine just because FDA licenses it or ACIP recommends it; state legislators are responsible to make their own decisions

and cannot pass the buck to FDA, ACIP or CDC, which only have power to recommend, but not mandate, the vaccines.

Then comes the question, why do ACIP and FDA so gratuitously put so many vaccines on the "recommended" list for all children? *JAMA*'s editorial reveals the answer: these recommendations are monetary decisions masquerading as medical decisions.

Here are *JAMA*'s words: "Since federal funding for vaccines is determined by the ACIP through the Vaccines for Children (VFC) program, whenever possible the ACIP should endorse funding for vaccines that physicians and parents wish to administer." In other words, the real purpose of ACIP and FDA recommendations is to release federal funds to buy the vaccines from the manufacturers. Remember that Rep. Dan Burton's investigation in June 2000 revealed many conflicts of interest among those who sit on federal panels where they can approve the recommendations that trigger the federal funds.

JAMA issues a stern caveat to the states: "All vaccines that are licensed and recommended for use in children should not necessarily be legally mandated for day care or school entry. Each state needs to assess each vaccine individually. . . . States should determine whether the disease to be prevented by the vaccines is highly contagious, results in significant morbidity and mortality, and poses a major health problem to both the individual and the community."

It's obvious that those are not the criteria used by the ACIP and FDA in their pronouncements. Many states are now amending their compulsory vaccination laws to add hepatitis B and chicken pox. An independent assessment of these vaccines by a state is unlikely to conclude that they meet the criteria set forth by *JAMA*.

Rep. Burton should hold more hearings to expose the government's vaccine licensing/recommendation/mandate process. Meanwhile, since the government's decision-making procedure is not only defective but suspect, we need a philosophical exemption in every state so that decisions can be made by parents whose motive is the health of their children, not promoting government purchases of vaccines.

Independent judgments by states and consumers might have helped to avoid past blunders like the rotavirus vaccine embarrassment last year that caused injuries to so many babies. At a minimum, a philosophical exemption in every state would create a market demand for improvement of vaccines.

Recall Defective Tires, But Not Vaccines?

A July 18, 2000 hearing of the House Committee on Government Reform produced evidence about the health dangers from vaccines containing thimerosal (mercury). Babies who are injected with the vaccines specified on the Universal Childhood Immunization Schedule, which are typically delivered in four to six shots during one doctor's visit, may receive 40 times the amount of mercury that is considered safe under Environmental Protection Agency (EPA) guidelines.

An independent evaluation conducted by the National Research Council confirmed the EPA guidelines as accurate, and the FDA's own website states that "lead, cadmium, and mercury are examples of elements that are toxic when present at relatively low levels." Credible testimony was also given regarding the possible relationship between symptoms of mercury poisoning and the skyrocketing rate of autism, now occurring in one in 500 children nationwide.

Committee Chairman Dan Burton sent letters to HHS Secretary Donna Shalala and the Food and Drug Administration (FDA) asking for the recall of all thimerosal-containing vaccines. His requests and those of parents of vaccine-injured children have been ignored. This is despite the fact that the FDA admits that the vaccines on the Childhood Immunization Schedule are all available in a thimerosal-free version.

Apparently, the FDA is not planning to recall any of the 50 thimerosal-containing vaccines but only suggests a "phase out" over time, thus allowing the pharmaceuticals to unload their defective merchandise on unsuspecting children. For years to come, these toxic vaccines will continue to be injected in babies in public health clinics, doctor's offices, and managed care facilities.

It is unconscionable to continue to put thousands of babies every day at risk from mercury poisoning, especially when the government is recommending use of these vaccines and the schools are making them mandatory, and when safe alternatives are easily available.

Leaving dangerous vaccines on the market so that the pharmaceuticals can continue to receive revenue from current inventories (instead of ordering a recall, as happened with tires) seems to be the pattern. Even after it was known that oral polio and whole-cell pertussis vaccines caused a higher rate of adverse reactions, clinics and doctors continued to use their supplies for years rather than pitch them in favor of safer vaccines. If there is any reason for HHS and FDA to continue to put thousands of babies at risk from dangerous vaccines other than to protect the profits of the powerful pharmaceuticals, we'd like to know what that might be.

Should Schools Force Medical Treatment?

■ In Utica, NY, parents of 77 middle schoolers were warned in October 2000 that their children would be taken and turned over to Child Protective Services for neglect unless they were vaccinated against hepatitis B within two weeks. There was no emergency, no epidemic of hepatitis B against which children need to be protected, and no evidence that hepatitis B is being transmitted at school.

The "emergency" was that the school district would lose a substantial amount of state funding if students did not comply with the vaccine mandate. So school district physician Dr. Mark Zongrone, giving his financial (not

medical) diagnosis, said, "We refuse to let that happen."

How did we get to a circumstance in America where a school, for its own financial self-interest, imposes medical treatment on children in opposition to their parents' wishes? Is this America or Nazi Germany? Hepatitis B is primarily an adult disease spread by multiple sex partners, drug abusers, and those in occupations where they are exposed to blood. Unless the child is born to an infected mother, children under the age of 14 are three times more likely to die or suffer adverse reactions from the hepatitis B vaccine than from the disease itself.

■ Parents of two students in separate schools filed suit on January 24 against the New York City Board of Education, claiming that it violated state and federal law by refusing to grant religious exemptions to forced inoculations. New York law requires schoolchildren to be injected with a long list of various vaccines, but allows both medical and religious exemptions.

Seventh grader Catherine Rotella refused the hepatitis B vaccination, asserting a religious exemption. She was sent to the administrative office and her parents were called to take her home. After she missed several days, the school demanded an affidavit from the family's clergy, which Catherine's father obtained. After she returned to school, two security guards barged into the middle of a class and physically escorted Catherine to the principal's office where she was denied the religious exemption and not allowed to return to school without the vaccination.

Second grader Maja Leibovitz was evicted from school last November 16 because she had not been vaccinated, even though her parents, Christian Scientists, claimed a religious exemption. The principal said he would hold Maja back a grade because she was not attending school, and then called Child Protective Services, claiming that the mother was guilty of educational neglect for not placing her child in school.

On January 26, a federal court ordered the New York City Board of Education to allow these two students to return to school. They were represented by Liberty Counsel of Orlando. Why did it take a lawsuit to get the school to obey the law?

Can a Court Order Kids to Take Drugs?

Can a judge constitutionally order a controversial drug to be given to a child over the opposition of his parents? Such action by a Family Court Judge in Albany, NY has touched off a national debate pitting public schools and the courts against parental rights.

Seven-year-old Kyle Carroll of Berne, NY, was diagnosed by a psychologist as having ADHD (Attention Deficit/Hyperactivity Disorder) and a physician prescribed the psychotropic drug Ritalin. The boy soon exhibited two of the drug's common side effects, sleeplessness and appetite loss. When Kyle's parents told school officials they wanted to temporarily discontinue the medication, they got a visit from the Albany County Child Protective Services and a petition to appear in court. The school district accused the Carrolls of "educational neglect" and they received what amounted to an order from Judge Gerard E. Maney to start using Ritalin again.

Under what was described as "at least the theoretical threat of having their child removed from their custody," the Carrolls agreed to "an adjournment in contemplation of dismissal (ACOD)." There was no fact-finding hearing before Judge Maney, no testimony taken, and no written decision rendered. According to law guardian Pamela J. Joern of Albany, who supported the school's position, "The consent ACOD directed the parents to comply with the doctor's treatment regimen, which was a prescription for Ritalin. They could get a second opinion, but they couldn't ignore the problem."

In order to avoid a prolonged court battle, the Carrolls compromised, which is usually what happens when parents are subjected to intimidation by state child protection agencies. The injustice of Judge Maney's decision will go unreviewed by higher courts, but the Kyle Carroll case has kicked up a storm of protest on the internet.

This case underscores the need for better medical privacy protection in order to safeguard against government intervention in personal medical decisions. A family's decision whether or not to use Ritalin is not the government's business. This judicial activism would never be known outside of the local community if it were not for the flow of information on the internet.

Ritalin does not treat an objective physical illness as, for example, insulin treats diabetes. Ritalin is a serious drug used to control behavior problems and is very attractive to the schools because it makes the child more likely to shut up, sit down, and do what he's told. There are some 3.8 million schoolchildren, mostly boys, who are said to have ADHD, according to the American Academy of Pediatrics. Estimates are that most of them are on Ritalin or similar psychotropic drugs.

The number of children labeled ADHD and taking Ritalin has greatly increased since 1991 when ADHD was covered under the Individuals with Disabilities Education Act (IDEA), a federal program that brings more funding to public schools in order to provide extra services. Under IDEA, the school is required to craft an Individualized Education Plan (IEP) to accommodate each child, which may include drugs prescribed by a medical doctor, and that's how Kyle happened to be given Ritalin.

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