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Vaccine Practice Payment Schedules Create Perverse Incentives for Unnecessary Medical Procedures – at What Cost to Patients?

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ABSTRACT

No published assessment of revenue variation associated with variance in pediatric vaccine uptake exists. Using data from patients in a pediatric practice that provides full-service with informed consent, we provide a detailed analysis of the financial realities of respecting informed consent and allowing parents to exercise their legal right to refuse some or all pediatric vaccines. The data from a 30-day period of billing were tracked and analyzed via superbills, noting vaccines that were ordered and those that were refused. Considering that other practice income covered all operating expenses; these numbers reflect actual profits (from vaccines given) and losses (from vaccines refused). Patients in the practice exhibited increased refusal of some or all vaccines over a period of approximately ten years. These real-world data show losses would exceed one million US dollars for a practice that bills out just over 3 million (gross revenue). With pediatric administrative overhead running 60–80%, it becomes clear that the financial incentives to vaccinate are now a matter of survival for pediatric practices.

Keywords: *California SB277, CDC vaccination schedule, Common Federal Policy 745, insurance payment schedules, pediatric practice survival, perverse incentives, pharmaceutical lobbyists, protection of human subjects, quantity versus quality in health care, voluntary informed consent, vaccine profits*

Introduction

Incorrectly oriented payment structures can lead to perverse financial incentives which can, in turn, lead to reduced time per patient (Campbell, 2015), inappropriate homogenization of healthcare options (Lyons-Weiler, 2015), skyrocketing healthcare costs (Packer, 2015), reduced scholarly initiative and entrepreneurship among physicians (Goodman, 2007), and the fossilization of suboptimal algorithmic insurance codes inconsistent with current medical science (Cook, 2015).

Perverse incentives have been recognized in the structuring of medical practice norms for some time now. Regardless of the original intent, the practical consequences of certain incentives are known to lead to a reduction in the quality of healthcare. For example, the incentive to see a large number of patients during a given time period ("throughput" in pediatrician jargon) invariably presses physicians to reduce the number of minutes per patient per visit. The absence of reimbursement for the administration fee for vaccination at "well-child" visits (that do not actually result in administering one or more vaccines) is certainly a way to incentivize an increase in the distribution and receipt of vaccines. in general. The wisdom and necessity of pushing maximum vaccination as optimal varies with two other factors: (a) as shown in Table 1, there are large variations in the population-wide coverage across distinct pathogens (column one in the table) believed to be required to achieve "herd immunity", and (b) there are not yet any reliable biomarkers that would enable advance identification of individuals or families who are at elevated risk levels for vaccine adverse events (potentially life-threatening allergic reactions, for instance). So blanket coverage of all patients without regard for the characteristics of specific pathogens and their distinct interactions with the biochemistry of different individual patients is not universally the best approach.

Table 1. Targeted Pathogens, Basic Reproduction Number (R_0), and Estimated Coverage Required for Herd Immunity

Targeted Pathogen	R_0*	Estimated Coverage Needed to Achieve Herd Immunity = $1 - (1/R_0)$
Hepatitis B**	1	0.00%
Meningococcal C	1.28	21.88%
Influenza (H1N1)	1.6	37.50%
Ebola	1.7	41.18%
Hepatitis A	2.01	50.25%
SARS-CoV-2	2.6	61.54%
Respiratory Syncytial Virus	3	66.67%
Diphtheria	3	66.67%
Haemophilis influenza	3.3	69.70%
Mumps	5.5	81.82%
Polio	6	83.33%
Smallpox	6	83.33%
Rubella	6.5	84.62%
Varicella	11	90.91%
Pertussis	14.5	93.10%
Measles	15	93.33%

*R_0, the basic reproduction number of the designated pathogen ("*R naught* or *R zero*") which is the estimated number of persons whom the first infected individual at ground zero can pass the infection to. The numbers tabled are from various sources and are offered only to show the enormous variability in the estimated infectivity of various pathogens in the CDC vaccination schedule.

**HepB <1 , 0.15 (Kretzschmar et al., 2002).

Pediatricians spend a great deal of time doing uncompensated work including patient phone calls, referrals, and, in some cases, their own accounting.

All along the way, insurance controls over medical practices place an additional layer of incentives — specifically so-called "quality measures" — that can penalize a practice for not reaching certain levels of vaccination. Reimbursement by insurance companies can incentivize high rates of vaccination by a bonus structure that provides higher rates of payment per RVU (Relative Value Unit). We submit that in the case of vaccines, the focus on quantity does not assure quality, neither at the practice level nor at the individual patient level. The use of *quantity*-of-medical-procedure delivery represents the worst possible incentive related to providing medical care to patients: the focus should be on the quality of health outcomes, not the quantity of distribution or receipt (the "uptake") of vaccines. Pediatricians honoring informed consent and allowing parents the option of not vaccinating or not following the CDC vaccine schedule, sacrifice profits. The extent to which a patient is vaccinated may help or harm their health and should not be considered a quality measure. Quantity does not equal quality. Such pediatricians also must work in fear of threats to their license to practice medicine, expulsion from group practices, and the loss of access to medical malpractice insurance.

Pediatricians are nevertheless compelled to abide by state laws and federal regulations regarding informed consent. Physicians who do abide by state, i.e., law brought to bear by the legislative process (as opposed to 'medical law' which does not involve elected representatives) are thus at times caught between doing what is lawful and doing as required by *de facto* "medical law". Physicians who abide by the requirements of the elected legislators at state and federal levels can risk being sanctioned by their medical board, or by a professional organization such as the American Academy of Pediatrics. They can face dismissal from their practice. Medical boards can threaten or remove their license to practice medicine altogether and insurance companies can drop these physicians and their entire clinics from insurance contracts based on so-called "quality measures" that merely look at the quantity of vaccinations administered in the practice and received by particular patients.

What happens when a physician adheres to state and federal requirements governing informed consent? One of us (Dr. Paul Thomas) has been targeted for providing alternative vaccination options that reflect a balance of risk between the emerging new knowledge on whole-body toxicity of aluminum — a risk incorrectly minimized by the FDA, as outlined in a peer reviewed study in 2018 — and the desire of some patients to vaccinate, or not. Others in pediatric practices have adopted draconian strategies to maximize vaccine acceptance — while denying awareness of financial incentives to vaccinate. The AAP has sanctioned the discharge of patients to improve vaccination rates in order to maximize the percentage of children in a practice who receive ALL of the vaccines recommended in the CDC pediatric schedule. This has led to calls for consideration of coercion to vaccinate (Colgrove, 2016) — a clear violation of federal regulations requiring informed consent for post-market vaccine safety clinical studies. These regulations afford special protections for children and pregnant women, and yet women who are offered TdaP and the influenza vaccine during pregnancy are never told they are part of a long-term "pharmacovigilance" safety trial. They are not told that the safety studies for vaccines used during pregnancy often provide insufficient data on fetal deaths and birth defects that occur after the use of one or more vaccines. They are not told that the package inserts for these vaccines specifically acknowledge that the childhood vaccines are

not tested for safety during pregnancies. Physicians who do not or cannot understand the science they tout as 'rigorous' cannot be blamed for accepting the language proffered by the CDC. If they know, for example, that in spite of CDC's emblazoned website that reads "Vaccines Do Not Cause Autism", the CDC focused their final conclusion on an Institute of Medicine (IOM) report that only reviewed evidence of a potential link between MMR vaccines and autism (IOM, 2012). In their report they judged that there was insufficient evidence to assess any causal relation that might conceivably exist between autism and the diphtheria toxoid, tetanus toxoid, or acellular pertussis vaccines. With respect to MMR data, in 22 studies that were judged relevant, the IOM rejected 17 as fatally flawed, and based their conclusion of no association on just 4 of those studies, one of which they acknowledged as "underpowered" — that one could not have found a relationship with autism even if the MMR was causing it.

The IOM (2012) concluded that the "*epidemiological evidence is insufficient or absent to assess an association between diphtheria toxoid*-[containing]*, tetanus toxoid*-[containing]*, or acellular pertussis-containing vaccine and autism*". That fact was affirmed in later legal proceeding against the CDC by the Informed Consent Action Network (ICAN, 2020). Given that only the MMR vaccines have been studied for association with autism, pediatricians have acquiesced to the paternalism of CDC pronouncements. They have usually (but not universally) embraced conflicts of interest and are compliantly engaged in the profit-making business of administering all the vaccines according to the CDC schedule.

Detailed Financial Outlays – and the Cost of Honoring Informed Consent

What are the financial incentives for pediatricians, family practice doctors and anyone for that matter who gives vaccines and profits from doing so? Also, what is the cost to a clinic that honors informed consent, and accepts patients known to have been discharged (abandoned) by practices that insist that parents give all the vaccines on the CDC schedule to all those patients that are permitted to remain with that practice?

To answer these questions in a real-world setting, we looked at every patient encountered in a large pediatric practice in Oregon over a 30-day period from mid-August to mid-September 2019. This practice accepts most insurance policies and most patients who seek care, without regard for the parents' preferences when it comes to vaccines.

There are three types of encounters in this practice with respect to vaccinations:

1. "Well child visits" where vaccine status is routinely reviewed, the CDC schedule is recommended, and then after informed consent the child may get no vaccines, one, or several vaccines.

2. "Shots-only" visits. In this practice, many parents prefer to give only one or two vaccines at a time, so nurse-only visits for vaccines are common.

3. "Sick visits" (or other complex visits) where vaccines could be given but typically are not.

For each of these visits where the informed consent process took place, the parent or guardian signed a vaccine refusal form that listed each of the recommended vaccines according to the CDC schedule. This form thus documents those vaccines that would typically have been given in most

standard pediatric practices and was used to tabulate the vaccines given as well as the vaccines recommended but refused by the parent or guardian of the child. While some presume that "standard of care" assumes that booster doses are harmless and are necessary, patients who test positive for antibodies against a given pathogen are not re-vaccinated, and unnecessary procedures are avoided.

Every medical practice has a unique contract with insurance companies, so the reimbursement for vaccines differs somewhat from practice to practice. There are two potential sources of profit to a clinic from vaccines. The first is the difference between the cost of purchasing the vaccine from the manufacturer and the amount of reimbursement from each insurance company for those vaccines. This can be considered the "mark-up" on vaccines. This typically results in a very small profit.

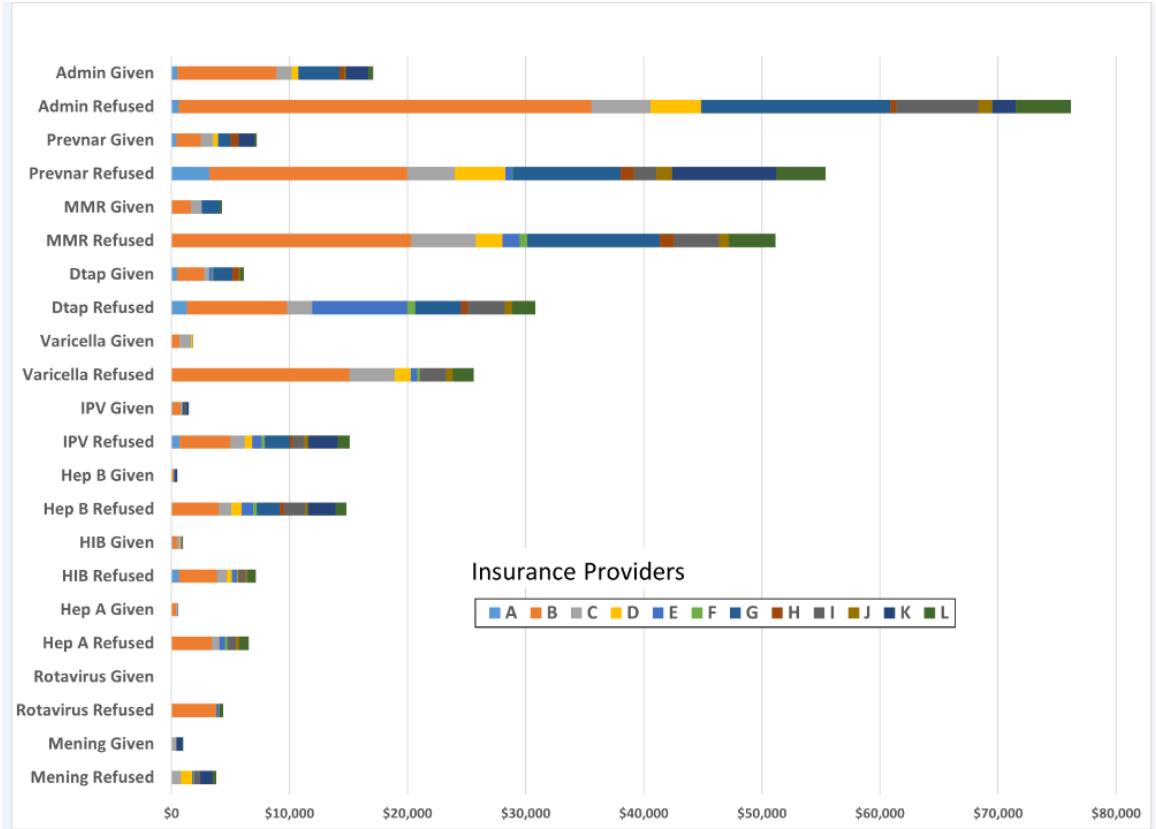
The second source of profit from vaccines comes from the administration fee (abbreviated in the jargon the "admin" fee). On any given day, the "first antigen" in a vaccine is reimbursed at a higher rate than any subsequent antigens. Multivalent vaccines are often used containing some combination of antigens — such as the diphtheria, tetanus, pertussis (DtaP) vaccine, which has three distinct antigens, or the measles, mumps, rubella (MMR), which counts as three, or if varicella is added as in the MMRV, four, and so on. For the sake of illustration, a 2-month at a routine "well-child visit" (one primarily for the purpose of vaccination) can serve as an illustration. If the practice is following the CDC schedule, the child will receive the IPV (polio), DTaP, Rotavirus, Hib, Prevnar, and Hepatitis B vaccines — 8 antigens from the perspective of reimbursement. Using an average of $60 for the "first antigen" and $30 for the rest, the admin fee for this visit would be $60 + (7 X $30) = $270. Taking account of the whole CDC schedule including the vaccines given at birth, 2 months, 4 months, 6 months, and 12 months costs on the CDC recommended vaccine schedule can be estimated as in Table 2.

Table 2. Estimated Outlays for Well-Child Visits on the CDC Schedule

Visit	Vaccines Recommended	Outlay
Birth	Hepatitis B	$60
2 Months	Hepatitis B, IPV, DTaP, Hib, Prevnar, Rotavirus	$270
4 Months	IPV, DTaP, Hib, Prevnar, Rotavirus	$240
6 Months	Hepatitis B, IPV, DTaP, Hib, Prevnar, Rotavirus, flu	$300
12 Months	MMR, Varicella, Hepatitis A, flu	$270
	TOTAL	$1,140

If the total amount from Table 2 is extrapolated to 30 newborns a month, it represents a revenue to clinics such as the one in the illustration, at $410,400 from the admin fee alone, and this only during the first year of life. Of course, there are added profits from the mark-up on the vaccines and any other income generated from the "well-child visits" themselves. To be fair, the extensive time-consuming education that should go into each visit, combined with the high overhead for full-service pediatric practices that provide total care (free advisory nurses, coordination of care and referrals, etc.), the only real profit is the admin fee. The full CDC schedule delivers at least 71 vaccines to every child by the time they are 18 years old. That represents 40 more vaccines with many of these being reimbursed at the "first antigen" rate. It is very probable that a busy pediatric practice might be making or losing a million dollars a year, just on the admin fee alone depending on adherence, or non-adherence, to the principle of informed consent.

Figure 1.. Revenue received, or not received in a pediatric practice of approximately 13,000 active patients (active patients have been seen in the past 2 years) based on patient acceptance or refusal through the process of bona fide informed consent from all reimbursing medical insurance carriers. The break-down by vaccine shows patient preference per vaccine type. The aggregate administrative fees outpace revenue from any single vaccine.



Real numbers can enable us to assess the exact profits and losses for a pediatric clinic that honors informed consent and thus ends up attracting families discharged from other practices for not following the CDC recommended schedule. Since contract details are proprietary, in Figure 1, the

actual reimbursements received are plotted but the insurance companies are anonymously designated as A–K with the smaller companies lumped together in group L. For each patient seen during this month the actual profits and losses when vaccines were administered or refused is tabulated and plotted with color coding.

Pediatric overhead costs, i.e., costs not involved in the direct care of pediatric patients, have traditionally run 60% to 80%. When the losses incurred for practices that honor informed consent are considered, it is easy to see how overhead would overrun any potential profits and make such a practice unsustainable. Indeed, around the country many if not most practices that honor informed consent have either gone out of business or had to change their business model to one of a concierge practice, or one that provides other unique services.

Should pediatricians be recommending, or worse, coercing their patients to receive and pay for vaccines out of the financial necessity of the practice? With the financial incentive to vaccinate, and to give as many as possible, it is unsurprising that many pediatric practices discharge or refuse to accept new patients who do not agree to follow the CDC recommended vaccine schedule.

When Dr. Paul Thomas was in medical school, 1981-1985 at Dartmouth, medical students were warned about the ethics of paternalism. It was drilled into our heads and hearts that it was not only unethical but poor medicine to take the position that "doctor knows best, so just do it my way or else". Sadly, in the world of vaccines, where there is now so much information on the dangers of hyperimmune reactions, mast cell activation, and other complications associated with neurodevelopmental delays, we still have a medical culture in which the likely role of nearly all pediatricians is incentivized by the CDC vaccine schedule — as if it were the only option. This is the most dangerous kind of decision-making by fiat.

Have we not learned from Nuremberg after World War II that "voluntary informed consent of the human subject is absolutely essential"?

> In 2005 the UNESCO Universal Declaration on Bioethics and Human Rights reiterated this important principle: "Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on ***adequate information***" (emphasis ours).

Our focus is on incentives to promote vaccination quantity without regard for objectively measured health outcomes. It is not enough to have all conflicts of interest displayed clearly out in the open — they must be eliminated whenever possible to ensure professionalism (Bernat, 2012). Doctors who recommend unnecessary procedures for which they benefit financially are probably less open to learning about problems that arise from those recommendations. On the contrary, it is only doctors who respect a parent's choice, regardless of revenues coming to the practice, even if compliance with the principle of informed consent results in a personal financial loss, are practicing ethical medicine. They must, however, do so despite the allure of the perverse financial incentives, precisely the kind we have illustrated here, that are fraught with conflicts of interest.

What perhaps complicates and polarizes the vaccine debate even further is the fact that our institutions of higher learning, professional associations and indeed the government agencies and media are funded by the very companies that profit from vaccines and pharmaceutical sales (Liu et al., 2017; Wong et al., 2017; Dal-Ré et al., 2019; Guo et al., 2021). These entities are, like our pediatricians, deeply conflicted by the perverse incentives we have documented here. Thoughtful

medical practitioners are led to wonder, can we trust the journal articles we read when we know they are sponsored by the very conglomerate of agencies sustaining and promoting the perverse incentives we have documented here? Of course, we need science, and the very nature of scientific inquiry is such that it is always evolving, but the CDC has declined to conduct a fully vaccinated vs. unvaccinated study, leaving it up to independent researchers to address the all-important question: are vaccinated children less healthy than unvaccinated, as indicated by recent studies conducted by non-stakeholders (Mawson et al., 2017; Hooker and Miller, 2020; Lyons-Weiler and Thomas, 2020)? To ignore this question is to march toward a future of an ever-expanding vaccination based on something other than science.

California's SB277 and Dr. Bob Sears

In the meantime, physicians who respect and abide by the principle of informed consent are being persecuted and punished for doing so. It appears that the pharmaceutical lobby is bent on restricting the rights to informed consent, particularly focusing on the most populous states in the US. Over the past few years, one pediatrician in California, Dr. Bob Sears, was targeted ahead of new legislation: SB277 was a law designed to bring California patients and pediatricians under the boot heel of the pharmaceutical lobbyists. It mandated the CDC vaccine schedule for all children in all contexts. According to the California Coalition for Vaccine Choice it said, "NO SHOT. NO DAYCARE. NO SCHOOL." When signed into law, SB 277 became "the most stringent vaccine mandate in the United States" ("No Shot. No School. California SB 277 Mandated Vaccination EVERY CHILD every vaccine," 2020).

Before the law was passed, Dr. Bob Sears had granted vaccine exemptions to two siblings because one of them had a severe medical condition that research has shown can get worse with ongoing vaccination. The other child did not have the condition at the time of informed consent, but the child's father did. Exemption for reasons in a family's medical history was a right guaranteed under California law prior to the passing of SB277. Dr. Sears also provided an exemption to a child with a family member who had acquired a severe permanent neurological injury after being vaccinated. Again, family history of reactions was specifically allowed by an amendment in the 2015 version of SB277 in order to get that law passed that year. The family being allowed exemptions by Dr. Sears is a perfect example of why the pharmaceutical lobby wrote SB277 in the first place. They were aiming to quash all possible exemptions and to force the CDC schedule on every child in California. As a last straw offense, Dr. Sears had also exempted a teen who had a severe reaction to an infant vaccine. Her own doctor told her to opt out of that vaccine, and Dr Sears agreed she should be exempt from the teen booster dose. CDC's Vaccine Information Statements point to pertussis-containing vaccines as ones that require consultation with a physician if there has been a prior adverse event (CDC, 2020). At the time of the latter exemption, Dr. Sears, again, was following the letter and spirit of California law.

Dr. Marcia Angell, MD, was the editor of the most prestigious medical journal in America, *The New England Journal of Medicine*, for 20 years. In 2009, for the *New York Review of Books* she wrote the following assessment of the medical literature well-known to her: "It is simply no longer possible to believe much of the clinical research that is published, or to rely on the judgment of trusted physicians or authoritative medical guidelines. I take no pleasure in this conclusion, which I reached

slowly and reluctantly over my two decades as an editor of *The New England Journal of Medicine*." Her title encapsulated the whole story: "Drug Companies and Doctors: A story of Corruption" (Angell, 2009).

Post-Market Vaccine Surveillance: Uncontrolled Human Subject Trials

Pediatricians may be surprised to learn that the widespread practice of post-market surveillance studies to assess alleged "vaccine safety" consists of experiments with human subjects without any requirement of the usual informed consent for research with human participants. By contrast university and medical researchers for clinical studies of any other kind of drugs or procedures must measure up to strict enforcement of informed consent by Institutional Research Boards. The *de facto* exemption of vaccines from the informed consent principle violates provisions of the National Research Act [Title II, Public Law 93-348], Regulations for the Protection of Human Subjects of Biomedical and Behavioral Research [45 CFR 46] and revisions of various regulations, rules, and laws ([21 CFR 50, [21 CFR 56], [45 CFR 46 Subpart D], [10 CFR 745].

Pregnant women and unborn babies are afforded special protections by [45 CFR 46 Subpart B], and post-birth children are afforded additional protections by [45 CFR 46 Subpart D]. Yet the rights of pregnant women (and their unborn babies) are violated with each and every vaccine administered to them because not only is there a paucity of pre-licensing clinical trials, but vaccines are never pre-tested for safety with pregnant women before they are licensed and are rarely examined after licensure for safety with mothers or their unborn babies.

Typically, studies such as the one by Eaton et al. (2018), will compare one vaccine such as the H1N1 vaccine against another such as the trivalent influenza vaccine (TVI) in 5,365 pregnant women vaccinated at Kaiser Permanente in Northern California in the years 2009-2010. That study and others like it, merely show that the two vaccinations were about equally likely to cause such adverse events as "preterm birth (<37 weeks), very preterm birth (<32 weeks), low birth weight (<2500 g, LBW), very low birth weight (<1500 g), small for gestational age, spontaneous abortions, stillbirths and congenital anomalies" (p. 2733), estimated to be about 7 morbidities per 1,000 for each of these vaccinations. Nevertheless, pregnant women are regularly pressured by the medical profession to get vaccinated against influenza and other pathogens (FDA: Vaccines for Use in Pregnancy).

The "Common Rule" of Federal Policy for IRB Approved Research[1]

While it is true that the Common Federal Policy for the Protection of Human Subjects ("Common Rule" [10 CFR 745] Sec 745.103(b)(3) allows the relaxation of the requirements for informed consent during emergencies, none of the suspended rights were ever revoked by subsequent legislation. In fact, the Common Rule re-asserted safeguards both for informed consent, and for

[1] Some this material was discussed extensively in an on-line article written for the Children's Health Defense by James Lyons-Weiler (2020). Key points cited there are presented here with specific sources as noted.

special protections against coercion as shown in the following taken from the requirements for IRB approval:

> [Common Rule] §46.116 General requirements for informed consent.
>
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>
> Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Notably the foregoing requirements were bolstered by § 46.111 Criteria for IRB approval of research under which paragraph (b) says:

> When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

Next we provide some of the text from what has come to be known as the "Nuremberg Code" coming out of the trial of Nazis who had "participated in the killing of physically and mentally impaired Germans and who had performed medical experiments on people imprisoned in concentration camps" during World War II ("The Nuremberg Code," 1946-1949). The following quotations are from the memorandum submitted on April 17, 1947 by Dr. Leo Alexander to the United States Counsel for War Crimes. It led to the following preliminary remarks and ten bullets that are now what is known as the "Nuremberg Code":

> The great weight of the evidence before us is to the effect that certain types of medical experiments on human beings, when kept within reasonably well-defined bounds, conform to the ethics of the medical profession generally. The protagonists of the practice of human experimentation justify their views on the basis that such experiments yield results for the good of society that are unprocurable by other methods or means of study. All agree, however, that certain basic principles must be observed in order to satisfy moral, ethical and legal concepts:
>
> 1. The voluntary consent of the human subject is absolutely essential.
>
> This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.
>
> The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

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 experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.

4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.

6. 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.

7. Proper preparations should be made, and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

9. 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.

10. 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.

Rights to Informed Consent or Refusal of Medical Procedures

Under US law, all individuals, and legal wards (custodians) of children have the right to choose or refuse medical procedures. The doctrine of informed consent is based upon the right of every individual to determine what shall be done to his or her body in connection with medical treatment. To exercise this right, the patient is entitled to information of a sufficient nature to allow him or her to make an informed decision on whether or not to consent or refuse treatment. Because patients are entitled to this information, physicians have a duty to make reasonable disclosures to their patients about the risks associated with proposed treatment. The duty to obtain a patient's consent for treatment rests on the patient's treating physician. Hospitals, nurses, surgical assistants, and referring physicians do not owe this duty to their patients. The treating physician's duty to obtain a patient's informed consent cannot be delegated. The duty is not eliminated, lessened, or spread by having the hospital nurse secure the patient's consent prior to the procedure.

Informed consent is a federally guaranteed right, doubly secured by state legislation in some instances. By which type of law will America be ruled? Will it be governed by medical boards consisting of non-elected persons dictating decrees from some government entity such as the Advisory Committee on Immunization Practices (ACIP, a surrogate of the CDC)? Or will state and federal legislation prevail as provided by elected representatives of the people and guaranteed under the United States Constitution?

Financial incentives for quantity-based performance in pediatric practices — ones that require the one-size-and-one-schedule-fits-all while health outcomes are ignored — are ethically unacceptable to

sensible pediatricians and their patients (Kresowik et al., 2013). They pervert the purposes of pediatric medicine and corrupt its foundations (Weeks, 2015). At the crossroads to which we have come, the question is whether ethics or profits will prevail.

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