Tuskegee-Style Medical Deceit Still Overrules Human Research Protections: The recent baby-suffocating SUPPORT experiment and its context Peter Aleff

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A judge in Alabama asserted recently that medical researchers have the right to expose their human subjects to knowingly harmful and even fatal experiments without their or their parents' informed consent. This gives official approval to the many violations of its much proclaimed ethics codes that the medical profession routinely committed, including the infamous *Tuskegee Study* of syphilis that had long been condemned as a textbook example for those same abuses.

- 2.) Disposable babies maimed and killed in the SUPPORT suffocation experiment Medical researchers in 23 U.S. hospitals, led by the *University of Alabama Birmingham* Hospital, not far from Tuskegee, deliberately restricted from 2005 to 2009 the oxygen breathing help for half of the 1316 premature babies enrolled in their SUPPORT suffocation experiment; they thereby predictably killed 23 "extra" babies in their low-oxygen group. The Universities headed by the Chair and Vice Chair of President Obama's *Bioethics Commission* actively participated in this blatant violation of all medical ethics codes but that *Commission* then falsely reassured the President and the American public that the current regulations offered sufficient protection against such abuses. The researchers had lied to the parents about the risks because obtaining their mandatory informed consent would have been a bothersome, expensive, and counterproductive "defensive documentation" that would have interfered with their research. Many so-called "bioethicists" as well as the Director of the *National Institutes of Health* defended this deliberate crime of the researchers although their experiment design amounted to premeditated harm for the babies and even murder.
- 3.) The failure of the legal system to address the SUPPORT abuses

  The parents of three babies harmed during the SUPPORT experiment brought a malpractice suit against the lead researcher at the University of Alabama Birmingham and the members of the Institutional Review Board who had rubberstamped the openly patient-abusing research protocol. However, the U.S. District Judge for this case accepted at face value the dishonest disclaimers of the defendants and their medical experts who falsely blamed the injuries of the plaintiffs on only their prematurity. They omitted to tell the Judge that the defendants' own team had published the clinical report about the SUPPORT experiment which attributed the 23 "extra" deaths in the low-oxygen group to the oxygen restriction with a probability of 96 percent, and that the lower rate of retinopathy of prematurity (ROP) incidence in that group compared with the high-oxygen group had a probability of 99.9 percent of being due to the experiment conditions. The Judge, in turn, ignored the legal rule about "preponderance of evidence" which requires a plaintiff's claim to be only "more likely than not", and she dismissed the plaintiffs' case as "mere possibility" despite the high probabilities that clearly met the legal standard for attributing the injuries to the experiment. One of

the mercenary "bioethicists" who had previously defended the SUPPORT experiment then crowed in the NEJM that the study had followed "high ethical standards" and had proved that the system worked.

#### 4.) "Truthiness" in the pediatric doctrine

The Judge also repeated uncritically in her account of the background to the SUPPORT experiment that blood oxygen levels as low as 70 percent were still safe for premature babies. This number was based on a deliberate misreading of a study cited by the Director of the *National Institutes of Health*. That study had included a group with a nominal oxygen level that low, yet its text made clear that the babies rarely if ever were at that low level but were generally kept near the top of their group's range. The Director of the *NIH* and two of his Department Directors had chosen to cite this low number to make the 85 to 89 percent level in the SUPPORT low-oxygen group sound safer than it actually was, despite a letter to the *NEJM* editor from some of the SUPPORT researchers themselves, including the defendant Dr. Carlo, that levels below 80 percent were strongly correlated with death. Such misrepresentations and refusals to accept facts are common in medical research, and the doctrine about ROP has even more than its fair share of these as well as of outright research frauds.

# 5.) The start of the alleged link between oxygen and baby-blinding

ROP began in 1940 in Boston, after oxygen had been given to premature babies for several decades without ever causing any eye damage. However, oxygen was the major means of helping the most vulnerable babies survive, and some eugenicist doctors at that time blamed the blinding on undesirable "defective germ plasm" which they wanted to eliminate by eliminating those babies. So they first started a smear campaign against "liberal" oxygen as an "undeserved subsidy", then they rigged a multi-hospital trial in which they withheld the breathing help for the first two days, and only then they enrolled the survivors of this brutal weeding. This strategy killed the most vulnerable babies who would have been most likely to develop ROP, and the "researchers" then announced falsely that they had virtually ended the blinding without increasing the mortality. This greatly touted wrong result immediately caused neonatologists around the world to severely ration oxygen for all preemies although this one study contradicted all previous experience and could never be replicated despite many attempts. It killed at least 150,000 babies in the first two decades of oxygen rationing, but this massacre was never investigated and still continues to some unknown and unadmitted degree.

The latest attempt to clarify this non-existing relationship between blinding and suffocation mortality with the \$20-million SUPPORT experiment predictably killed 23 "extra" babies but produced again no new knowledge. However, true to the hidden eugenic agenda, some "better dead than blind" nurseries lowered their oxygen supplementing to reduce the blinding although they knew this would kill more babies. This ongoing routine killing of premature babies without any objection from the "pro-life" embryo defenders highlights the absurdity of the current attacks in Congress on the use of

aborted fetal tissues from Planned Parenthood for necessary and legitimate medical research instead of incinerating them as medical waste. If those attackers were really pro-life, they would make efforts to stop the continued killing of born babies.

6.) Medical denials that the blinding is caused by the excessive nursery lighting
The ROP epidemic had started in the U.S. the year after the commercial introduction of fluorescent lamps, and the same parallel repeated itself after World War 2 in other industrial countries as those lamps became available there and the ROP epidemic broke out just as suddenly in their wake.

Industrial-safety researchers established that the most retina-damaging light is in the "blue-light-hazard" wavelength region from 430 to 440 nanometers. Virtually all fluorescent lamps emit a major part of their energy precisely in the middle of that most dangerous range, at 435.8 nm. The eyes of preemies are at their most vulnerable stage. The typical intensive care nursery lighting of 60 to 100 foot-candles exposes their retinae in less than 15 minutes to the amount of damage-weighted retinal irradiance that the U.S. Industrial Safety Guidelines have established as the danger limit for adult workers over an eight-hour shift. The presence of oxygen enhances the radiation damage caused by the blue-light-hazard, but oxygen alone does not create that damage.

A study in 1982 reduced the irradiation of the babies from 60 foot-candles to 25 ftc and drastically reduced the incidence as well as severity of ROP. However, critics did not like the result and quibbled with the before-and-after format of the study. To disprove it, they rigged their own experiment by patching the eyes of half the preemies enrolled but applied the patches only up to 24 hours after birth while knowing that it takes only a few minutes to cause the eye damage. Their knowingly false result that the nursery lighting does not affect the blinding is now the reigning dogma and continues the profitable blinding epidemic.

7.) Ending the cover-up of the euthanasia and ROP-blinding against premature babies The fake LIGHT-ROP trial as well as the Cooperative Study oxygen swindle need to be exposed and retracted before any progress can be made to end the ROP epidemic. Also, all babies need to be protected from the blue-light hazard of the fluorescent nursery lamps, for instance, with yellow filter coatings.

Many nursery doctors and editors of medical journals are strongly opposed to any examination of their blatantly false and fraud-based dogmas about oxygen causing ROP and alleged lack of eye damage from nursery lighting. This defensive wagon-circling attitude must be overcome and replaced by a culture of transparency and error-correction. Outcomes from all intensive care nurseries need to be published and compared to identify the trouble spots. This will give hospitals the now lacking incentive to improve those outcomes.

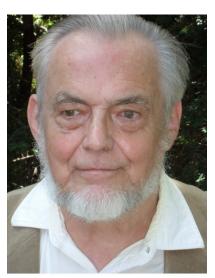
#### 1.) Smokescreens of "medical ethics"

On August 13, 2015, a U.S. District Judge in Alabama asserted the right of medical researchers to perform harmful clinical experiments of withholding needed treatment from human subjects without their informed consent. If this decision is allowed to stand, it will negate more than four decades of official condemnations for the U.S. *Public Health Service*'s infamous *Tuskegee Study* of syphilis which did exactly that, and it will condone many similar past medical crimes. That classic Tuskegee model of a scandalous study even led to the founding of the *Bioethics Center at Tuskegee University* with the mission

"... to inform national policies to prevent the reoccurrences of similar abuses in human health research and service to African American and other health disparity populations. Moreover, vigilance required to protect the public's health must be maintained by institutions trusted by vulnerable populations."

Yet, the lack of protection for the extremely vulnerable population of premature babies, many of whom are African American, endures unabated not far from this *Center*, and now even with the approval of the Alabama legal system. The efforts of that *Center* have not prevented the Hospital at the *University of Alabama Birmingham*, a two-hour drive from Tuskegee on I-85 and I-65, as well as 22 other hospitals in that same experiment led by that *University*, from repeating precisely the same withholding of needed therapy and lack of informed consent which led to the foundation of that *Center* to prevent just such a reoccurrence.

Guidelines for informed consent to medical interventions and human experimentation were established at least as early as the nineteenth century<sup>2</sup>. In a very public case in 1900, a German physician had been charged with violating that principle of informed consent, and at the end of the 1920s a series of unethical experiments in Germany that caused fatalities of children led to a public



Peter Aleff.jpg

uproar which then triggered the *Reich Ministry of the Interior* to issue in February 1931 the "Regulations Concerning New Therapy and Experimentation". These were among the most comprehensive research rules of the time and in some parts "even more elaborate than the later *Nuremberg Code*" before the Nazis' rise to power supplanted them in practice with their fascist brand of "ethics" that placed the alleged needs of society above individual rights and gave free reign to even grotesque medical research<sup>3</sup>.

Today, the best-known formulations for these basic principles of avoiding harm to research subjects and of obtaining their informed consent stand in the 1947 *Nuremberg Code* of medical ethics in human research<sup>4</sup>. This *Code* is a misleading relic from shortly after the revelations about the cruel and often fatal experiments of some German medical researchers on non-consenting people risked to

give a bad name to all medical research on humans. At that time, some American doctors felt they should at least pretend some concern for the human subjects of their research to restore those subjects' confidence in their treatment. They also wanted to divert attention from the still prevailing eugenic views which the Nazis had imported from the U.S. and Britain with the active support of physicians and philanthropists in those countries. The ruthless Nazi policies based on those eugenic ideas had harmed and killed many more people than all those heinous experiments combined<sup>5</sup>, and the eugenicists among the victors whose theories and examples as well as donations had led to those policies felt the need to hide their complicity while publicly disavowing the more eye-catching but less numerous medical research crimes.

Meant to be reassuring, the provisions of that *Code* include that the informed consent of all human subjects to medical research is absolutely essential, without fraud or deceit, and also that "no experiment should be conducted, where there is an a priori reason to believe that death or disabling injury will occur." This *Code* became the basis for the successive *Helsinki Declarations* of Ethical Principles for Medical Research Involving Human Subjects by the *World Medical Association* as well as for the related U.S. *Federal Regulations* for the Protection of Human Subjects, or "*Common Rule*".

All these solemn affirmations of human rights in medical experiments profess to minimize any risks to research subjects and to tell them openly about those risks, and they are still much touted in the U.S. and around the world as alleged guarantees for the ethical treatment of research subjects although medical researchers have routinely and grossly violated them and continue openly to do so. Among the many American examples of such transgressions are the notorious syphilis studies conducted by the U.S. *Public Health Service* in Guatemala and Tuskegee, the equally scandalous more than 430 Cold War *Human Radiation Experiments* performed from 1944 to 1974 which exposed thousands of unsuspecting civilians, including children, as well as duped military conscripts to sickening doses of nuclear radiation or secretly fed them radioactive materials in their food or by injection<sup>6</sup>, the deliberate infection of retarded children with hepatitis from 1963 to 1966 at the *Willowbrook State School*, the injection of live human cancer cells in 22 senile human patients in 1963 at the *Jewish Chronic Disease Hospital* and in over 300 at *Memorial Hospital* in New York<sup>7</sup>, and many other later cases of callous disregard for the rights and well-being of humans in American medical research<sup>8</sup>.

The medical community's lack of alarm about such frequent violations of its published ethical principles explains why, except for a very few of the most infamous Nazi medical experimenters judged by the victors in World War 2, none of the other offenders against the ostensibly proclaimed principles of medical ethics have ever been punished, not even any of the many Nazi doctors involved with the systematic euthanasia killing of "useless eaters" which murdered many more victims than the much publicized medical experiments. To the contrary, the *World Medical Association*, strongly influenced by the *British* and *American Medical Association*, chose as its President-elect in 1992 one of the German doctors, Prof. Dr. Hans Joachim Sewering, who was directly responsible for the transfer of 900 children into the Nazis' child euthanasia program. He had

to withdraw from that nomination only when many witnesses publicly testified against his denials that he knew his transfer orders amounted to those children's killing<sup>9</sup>. Similarly, two years after the above illegal cancer cell injections, the *American Cancer Society* elected the principal investigator in those ruthless wrongdoings, Dr. Chester Southam, as its Vice-President.

Also, updates on the openly unethical *Tuskegee Study* had been published regularly in the medical literature during its conduct without raising any objections<sup>10</sup>, and the American leader of the syphilis studies in both Guatemala and Tuskegee, Dr. John C. Cutler, received high academic honors during his later tenure as professor and acting dean at the *University of Pittsburgh Graduate School of Public Health*. After he died in 2003, this University even sponsored the *Cutler Memorial Lecture in Public Health* in his honor from 2007 to 2008<sup>11</sup> until a new dean had to react to a public outcry about their unacceptability.

This persistent disdain of the American medical community for its much advertised principles of "medical ethics" is again documented in a recently published *MedPage Today* analysis of 57 clinical trials conducted during the years 2010 to 2012 where 36 of these did not disclose to their subjects the serious risks of the medications to be tried; these risks were spelled out on the package inserts (which the research subjects usually don't see) but were omitted from the consent forms<sup>12</sup>.

# 2.) Disposable babies maimed and killed in the SUPPORT suffocation experiment

Consistent with the medical profession's indifference to its research abuses, the official reactions to those recurring violations were so far limited to government speakers giving lip service to the lofty principles embodied in that *Nuremberg Code* and its spinoffs. They used to convey disapproval of the abuses (but not of the abusers) and twice even led to much publicized Presidential apologies for older cases of medical misconduct even right while newer ones were being committed to the sound of those repetitive "never again" tirades. President Clinton apologized for the *Tuskegee Study* and the *Human Radiation Experiments* while the unethical and dishonest LIGHT-ROP experiment on premature babies was being conducted to continue their profitable blinding, as discussed farther below<sup>13</sup>. Similarly, the recent and even more brazen ethics breach of the knowingly fatal SUPPORT suffocation experiment on premature babies was still continuing right during President Obama's contrite public apologies for the earlier American medical research crimes in Guatemala<sup>14</sup>.

As part of his public condemnation of the U.S. syphilis studies in Guatemala, President Obama requested his *Presidential Commission for the Study of Bioethical Issues* to reassure him and the American Public that such abuses against medical ethics could no longer happen. As instructed, that *Commission* held a series of allegedly fact-finding public hearings and pretended to investigate this question. However, it ignored all the alerts about present abuses it received, and it then ritually produced the requested reassurance. However, that reassurance was a brazen lie because the Universities headed by the Chair and the Vice-Chair of that very *Commission* were still actively participating in the parent-deceiving and deliberately baby-killing SUPPORT suffocation experiment which was an even worse abuse against its research subjects than the Guatemala and Tuskegee

syphilis studies which the *Commission* was denouncing <sup>15</sup>. Those studies had at least not intentionally killed anyone. By contrast, the SUPPORT researchers deliberately increased the risks of death and severe injury for the babies they enrolled and thereby knowingly killed 23 of them, and they lied to the parents on the consent forms by denying the well-known existence of those risks <sup>16</sup>.

That SUPPORT experiment was conducted from 2005 to 2009 in 23 U.S. hospitals to restrict the oxygen breathing help for half of the 1316 enrolled premature babies, in the hope that this already often tried dangerous intervention might reduce their risk of eye damage from baby-blinding retinopathy of prematurity (ROP)<sup>17</sup>. Instead of using the entire commonly administered "standard of care" range of blood oxygen levels from 85 to 95 percent, the researchers tried to find the elusive but imaginary exact level that would avoid the blinding without killing many babies, an even theoretically impossible task because it does not account for the human variability among the subjects of their research and their individual conditions. Despite the known high risks of increasing the expected lethal damage from asphyxiation to maybe prevent the non-lethal condition of eye damage, and without establishing a control group to which to compare their results (a standard for competent trial design), they split the enrolled babies into two groups which were to receive 85 to 89 percent in the low-oxygen group and 91 to 95 percent for the high-oxygen recipients<sup>18</sup>.



Premature Baby on Ventilator.jpg (photo by author)

To achieve the "masking" of the groups required by the trial protocol, the supplier of the pulse

oximeters adjusted their displays up or down by 3 percent so that all showed the same range from 88 to 92 percent. This way, none of the care givers could know which baby was in which group, or what actual oxygenation level any one of them received. This masking of the groups in the experiment prevented the care givers from using their clinical judgment for adjusting the oxygen level to the individual needs of each baby; it is the equivalent of tampering with the altimeter in an airplane so that it shows three hundred feet less or more than the actual height above the ground and so misleads the pilots dangerously about the actual conditions for their landing.

However, just as those pilots would ignore their dials and in clear weather try to land their plane by sight, many of the neonatal nurses, as reported in some of the prior oxygen rationing experiments, likely reverted to the low-tech expedient of ignoring the oximeter numbers and turned up the oxygen when a baby became dusky until he or she again looked a healthy pink. Of course, this undeclared variation further defeated the researchers' unrealistic quest for some magical "Goldilocks" oxygen level number that would avoid the dangers of too little or too much.

The researchers in the parallel Canadian-run "COT" or "Canadian Oxygen Trial" experiment addressed this lack of reproducibility in the trial protocol and stated:

"Our trial has several limitations. Perfect adherence to the narrow target range of 88% to 92%, as displayed on the offset study oximeters, would have resulted in a difference of 6% between the true arterial saturations in the 2 groups. We observed barely half of this difference on days with at least 12 hours of supplemental oxygen. Caregivers may have tolerated saturations approaching the upper alarm limit more often than saturations approaching the lower alarm limit. Furthermore, we did not record exact times spent receiving supplemental oxygen for all study participants beyond the first 3 days. The distributions of saturations we report are therefore confounded by time spent breathing 21% oxygen [room air] when caregivers were unable to modify arterial saturations." 19

In other words, the COT researchers acknowledged that the nurses paid more attention to the visible status of the baby in giving more oxygen instead of blindly obeying the oximeter displays.

Similarly, a pediatrician posting a reader comment in the *New England Journal of Medicine* about the oxygen levels in the SUPPORT experiment said under the title "Sat targets vs. actual sats":

"At least 2 studies that I'm aware of documented poor compliance with GA-related  $0_2$  sat targets in NICUs. We all observe alarm limits re-set at night, alarms ignored or addressed after long delays, etc. Until response to pulse oximetry alarms becomes automated, the human element of NICU care (stretched ratios, break coverage, lack of accountability, etc.) confound any findings published on this issue."  $^{20}$ 

Yet, the SUPPORT account ignores these confounding factors and pretends that somehow the theoretical numbers were also the actual ones used in practice.

Despite these inherent inaccuracies which compromised any reportable results from their experiment, the SUPPORT researchers knew that their restricting the oxygen levels would increase the risks of death and of serious brain damage. They cited a British report from 1973 that the routine oxygen rationing practices introduced 17 years earlier had by then led to an estimated 16 deaths for each case of blindness prevented<sup>21</sup>. Similarly, the authors of the NeOProM umbrella study proposal, which included the SUPPORT experiment as well as COT and three other parallel studies in other countries, mentioned a well-known medical estimate of 150,000 premature babies killed from lack of oxygen in the first 20 years after the largest of the initial oxygen studies and its fatal recommendation to ration the life-saving gas<sup>22</sup>.

(Unlike the mostly non-fatal syphilis studies cited above, this even more ruthless and much more deadly introgenic mass killing was never properly investigated or publicly exposed; as discussed farther below, it continues today in a hidden and possibly reduced but still uncontrolled form.)

Both these groups of SUPPORT and NeOProM authors expressed the hope that better measurement techniques would meanwhile allow to somehow improve this outcome, but the examples they cited did not back up their wishful argument. The SUPPORT authors summarized a limited sample of studies in which lower oxygen levels had correlated with lower incidences of blinding, but for most of these the mortality had not been reported. However, in one of those that did count the deaths, a tighter monitoring of this breathing help had not affected the incidence of ROP but had increased the number of deaths by 8 and 11 per cent, depending on the birth weight group, with a probability of 94 percent that these increases in mortality were not statistical flukes<sup>23</sup>.

The SUPPORT authors openly admitted in their clinical paper that the safety of the infants in their trial was not assured:

"Although data from these studies suggest that maintenance of oxygenation at ranges lower than those previously used may decrease the incidence of retinopathy of prematurity, the safety of low target levels of oxygen saturation remains a concern."<sup>24</sup>

The NeOProM paper also stated that this trial design could cause 4 per cent extra deaths and/or severe brain damage for the expected benefit of maybe protecting some of them from blindness, and that the risks to their subjects were therefore neither minimized nor outweighed by the potential benefits<sup>25</sup>.

Yet, in open defiance of all applicable regulations and ethics codes, these rogue researchers proceeded anyway with their knowingly harmful experiment, and they told the parents nothing about the well-known predictable risks of either death or neurological injury or eye damage.

This glaring omission was intentional and not due to any putative uncertainty of the researchers. They knew that no parent could legally have agreed to enroll their child in a study with this risk of death, merely for an unproven hope of reducing the risk of blindness which is a non-lethal condition. Parents can make decisions about treatments for their child only if these are in the interest of that

child, and risking death to prevent eye damage is clearly not in his or her interest since even intact eyes would be of no use to a dead child in a dark coffin. Moreover, the *Nuremberg Code* as well as all subsequent declarations and regulations of medical ethics specifically forbid all researchers to expose their subjects to any risk of death from their research. As cited above, Article 5 of that *Code* states clearly:

"No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur". Article 7 adds "Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death."

Because of the legal and practical impossibility of obtaining any parent's informed consent for their "better dead-than-blind" research, the designers of this oxygen-withholding experiment had suggested already in 2003, in their initial discussions of the proposed experiment, to skip the informed consent formality. They said this "defensive documentation" would likely reduce enrollment or make that enrollment impossible to begin with if its risks had to be explained to the parents. Because it was clearly in violation of the regulations, they offered this suggestion obliquely and indirectly and discussed "the wisdom of collecting only the relevant, necessary data", then quoted approvingly this analysis from a 1998 article on the future of clinical trials:

"Requirements for large amounts of defensive documentation imposed on trials by well-intentioned guidelines . . . may, paradoxically, substantially reduce the reliability with which therapeutic questions are answered, if their indirect effect is to make randomized trials smaller or even to prevent them starting." <sup>26</sup>

This passage clearly reveals the researchers' utilitarian and illegal intention to disregard the requirement for informed consent because only this "defensive documentation" imposed by "well intentioned guidelines" would have prevented any or all parents from volunteering their babies for that knowingly fatal experiment.

And after the SUPPORT results had been published, some defenders of that criminal protocol claimed more prominently and now openly that the consent requirement in all the current *Codes* of medical ethics is a well-meaning but inconvenient and annoying hindrance against research projects where a full disclosure of the risks is likely to dissuade many or all potential subjects from participating. Those proponents of unfettered medical experimenting on unconsenting subjects complained again, but his time directly and without disguise, that obtaining consent was a bothersome, expensive, and counterproductive "defensive documentation" which would reduce the number of babies enrolled or could even prevent some experiments from ever starting. The title of their most recent paper even suggested that the consent requirement could be as deadly as a "python's embrace" in that it strangled potentially life-saving research and kept it from being conducted<sup>27</sup>.

This echoes, of course, the above cited comment about the Nazi doctors that these had placed the alleged needs of society above the rights of the individuals.

The lack of information about the risks of death and severe injuries on the parental consent forms to the SUPPORT experiment was therefore not due to any ignorance of those risks on the part of the researchers, or to their alleged incertitude about them, as they tried to claim when asked about their omission on the consent forms. Instead, it was due to their planned obfuscation of the known risks, and to their fascist-style disdain for the rights of their individual research subjects.

As a result, the SUPPORT researchers killed knowingly and with premeditation an "extra" 23 of the children in their low-oxygen group, and they computed a probability of 96% that this difference in deaths was not due to chance. This intentional treatment of human babies as disposable guinea pigs for medical research does not only violate all the relevant ethics *Codes* but it also appears to meet the legal definition of first-degree murder under Title 18 of the *U.S. Code* §1111.

These openly committed medical murders have so far remained unpunished.

Two years after being alerted to the obvious and glaring failure of the SUPPORT consent forms to disclose those serious risks<sup>28</sup>, and to the researchers' knowingly exposing the research subjects to an increased risk of death, the U.S. *Office for Human Research Protections* tried to give a weak slap on the wrist to Dr. Waldemar Carlo at the *University of Alabama Birmingham* as the lead researcher for this fiasco by sending him a "letter of determination". However, this mild rebuke addressed only the lack of information on the consent forms but did not even mention the deliberate killing of the babies. Then the *OHRP* held on August 28, 2013, a public hearing to request comments and clarifications about the need for consent and protection of human subjects in medical research, as if these were not already fully described in the applicable ethics *Codes* and *Regulations*. It also indefinitely suspended its attempted criticism of the violators when a number of so-called bioethicists as well as three top officials at the U.S. *National Institutes of Health*, including their Director, Dr. Francis S. Collins, protested to defend them.

These unconditional defenders of indefensible medical crimes falsely claimed that there had been no need to inform the parents because the intervention fell within the limits of the "standard of care" and did not add any risk. This was a blatant and quickly debunked lie because the entire SUPPORT experiment had been conducted to compare the risks of death and severe brain damage with those of mostly blindness in the low- and high-oxygen groups, and each of the narrower oxygen level ranges was associated with specific and well-known risks of death, brain damage, and blindness which the researchers themselves had described and discussed<sup>29</sup>.

#### 3.) The failure of the legal system to address the SUPPORT abuses

Unlike most of the earlier governmental reactions to medical ethics violations which at least feigned some of the usual official contrition customary upon the revelation of such abuses, Chief U.S.

District Judge Karon Owen Bowdre in the Northern District of Alabama, Southern Division, has now torn away even this fig leaf of claimed caring for the rights of research subjects<sup>30</sup>.

The parents of three babies harmed in that SUPPORT experiment – two with neurological issues and one with ROP – had brought malpractice charges against the eleven members of the *University of Alabama-Birmingham* Hospital's *Institutional Review Board*, against Dr. Waldemar Carlo, named as the principal investigator and designer of that research trial<sup>31</sup>, and against the Masimo Corporation, the supplier of the deliberately mis-adjusted oxygen metering devices used in the study.

In her summary dismissal of these charges on August 13, 2015, that home-team-shielding Alabama Judge exposed the naked truth that the purported protections said to be offered to human research subjects by this *Code*, by those formal *Declarations*, and by the elaborate *Federal Regulations* have still no legal standing in Alabama, the very state in which the textbook-model unethical *Tuskegee Study* had been conducted with the same now ritually condemned violations of those alleged protections. All these sanctimonious promises turn out to be just meaningless fictions that the researchers and their blindly rubberstamping *Institutional Review Boards* across the U.S. are now again lawfully allowed to ignore while duping the parents of the babies about the harm expected from their medical investigations. Moreover, in this current case that actively and directly inflicted fatal harm from intentional suffocation was even worse than in the *Tuskegee Study* where the harm had been caused passively and indirectly by non-intervention with an available cure.

To begin with, that gullible Judge ignored the notorious local history of deceptions by medical researchers which had made the word "Tuskegee" a world-wide shorthand reference to precisely such abuses. She accepted at face value the version of that SUPPORT experiment which the defendants and their profession-protecting experts described to her although this version differed starkly from the account their own team had published in the *New England Journal of Medicine*. The defendants and their neonatologist experts told the Judge dishonestly that the injuries suffered by the plaintiff infants were not caused by the research but only by their extreme prematurity. If they made these assertions under oath with the obligation to tell "the whole truth", as they likely did in their depositions before that Judge, they knowingly committed perjury.

Blaming prematurity alone for the injuries is like blaming airplane crashes merely on gravity. Both prematurity and gravity are underlying conditions without which the injuries would not have happened, but they are both insufficient to explain the injuries in the absence of other factors which are the actual and direct causes.

Just as they had lied to the parents on the consent forms by omitting to mention the known risks and by telling them that their child's participation in the "risk-free" and merely "information gathering" SUPPORT study would not hurt him or her in any way<sup>32</sup>, the defendants omitted to tell the Court the very relevant facts that the published results from the SUPPORT experiment attributed the 23 "extra" deaths in the low-oxygen group to the oxygen restriction with a probability of 96 percent, and that the lower rate of ROP incidence in that group than in the high-oxygen group had a

probability of 99.9 percent of being due to the experiment condition<sup>33</sup>. Yet, that Judge apparently neglected to consult this easily available clinical publication by the defendants' own team that would have allowed her to evaluate the blatant lies in their presumably sworn testimony.

The results for the neurological damage in that group were intended to be published, and three of the SUPPORT authors had stated in a September 23, 2010, letter to the *NEJM* that neurodevelopmental outcome data were expected between 2011 and 2014. However, as of September 27, 2015, these have not yet been published.<sup>34</sup> Death is the extreme form of that damage. Based on what is known about the gradual and cumulative effects of oxygen deprivation on the brain, it is to be expected that its lesser forms were even more prevalent in that low-oxygen group than this extreme, with an even higher correlation.

The Judge is apparently unaware of these published and easily verifiable high probabilities of causation for the injuries of the plaintiffs. She cites on pages 11 and 12 of her Opinion a legal principle which says:

"Proof which goes no further than to show an injury could have occurred in an alleged way, does not warrant the conclusion that it did so occur, where from the same proof the injury can with equal probability be attributed to some other cause."

The totally unsubstantiated allegation of "equal probability" does not apply to the SUPPORT results which attributed the tabulated injuries with overwhelming probabilities to the conditions of the experiment and not to any other cause. Moreover, the standard of evidence required in personal injury cases like the one at hand calls only for a "preponderance of evidence". This is described in many law dictionaries and articles on this topic, and most clearly in this passage from the *Nolo Law Library* discussion of law topics "The Burden of Proof in a Personal Injury Case":

"A plaintiff in a civil case -- including personal injury claims -- has a much lower burden of proof [than in a criminal case]: the plaintiff must convince the jury that it is "more likely than not" that the facts are what he or she says they are. "More likely than not" (or "by a preponderance of evidence") essentially means the jury thinks the chance the plaintiff's version of the facts are true is at least 51%, while the chance they are false is no more than 49%. Fifty-fifty odds are not good enough."<sup>35</sup>

The published odds of 96 and 99.9 percent certainly far exceed this standard, but Judge Bowdre calls them a mere "possibility". Despite this strong evidence, she does not acknowledge that the harm to the three plaintiff babies had "probably" been caused by the experiment, instead of just "possibly". She misrepresents the strength of this evidence by saying "correlation is not causation", although the published correlations far exceed the required odds. Her gross misrepresentations of the documented facts and of the law allowed her to claim that the plaintiffs had not proved the harm to the three babies was caused by the researchers.

That Judge also dismissed the injury of one baby from ROP by saying that this condition had not resulted in blindness, but she appeared unaware that the eye damage from ROP is significant even without blindness, and that it typically gets worse as the child gets older. The *National Eye Institute* explains on its website under the heading "Can ROP cause other complications?":

"Yes. Infants with ROP are considered to be at higher risk for developing certain eye problems later in life, such as retinal detachment, myopia (nearsightedness), strabismus (crossed eyes), amblyopia (lazy eye), and glaucoma. In many cases, these eye problems can be treated or controlled."<sup>36</sup>

This means that even in those best-case scenarios when the problems can be treated, this often involves repeated surgeries and less than optimal eyesight, or even later blindness from gradual retinal detachment. The Judge is wrong to ignore this injury and those expected complications just because the child with ROP is not (yet) blind. She is also wrong to uncritically accept the defendants' experts' false allegations that this baby's ROP was caused only by his or her prematurity and not by the SUPPORT research protocol, despite the 99.9 percent probability of it being due to that research, as stated in the defendants' team's own published report.

Similarly, Judge Bowdre used this same biased and uninformed reasoning about the probability of causation to dismiss the plaintiffs' complaint about the lack of informed consent, the breach of the defendants' fiduciary duty towards their research subjects, and their product liability claims against the maker of the intentionally miscalibrated oximeters. She wrote about those claims on pages 14 and 15 that

"... the Plaintiffs fail to establish injury and causation. As discussed above, Plaintiffs' claims based on an increased risk of past harm because this risk is not a legally recognizable injury. Plaintiffs' claims based on the injuries actually suffered similarly fail because the Plaintiffs are unable to establish that a lack of informed consent, a breach of fiduciary duty, or a defectively designed oximeter probably caused the infant Plaintiffs' injuries. Consequently, the Defendants are entitled to summary judgment on all of the Plaintiffs' claims."

In other words, if the lack of informed consent does not directly cause a provable injury then the researchers have no obligation to obtain that informed consent. This unusual interpretation would retroactively exonerate even the *Tuskegee Study* researchers because they did not cause the syphilis of their research subjects, they "only" failed to cure it when they could have done so.

Moreover, the Plaintiffs' alleged inability to establish the probable cause of their injuries is only due to that Judge's refusal to acknowledge the clearly computed probabilities of injury published in the official analysis of the experiment results in their own team's clinical paper, and to follow the commonly accepted legal rules about the "preponderance of evidence" in personal injury cases.

If her so biased *Memorandum Opinion* is allowed to stand, it will serve as a precedent for removing every researcher's obligation to abide by any ethics rules and *Code* stipulations about informed

consent. It will thereby re-open wide the floodgates to medical researchers' unrestrained free-for-all abuses and deceptions of trusting research subjects, as experienced during the notorious *Tuskegee Study* of syphilis.

That Judge's wrong but legally binding approval of these ethics violations will serve as a strong warning for all potential future research subjects to be wary of enrolling in any medical research studies because the lessons of Tuskegee have obviously not yet been learned, despite four decades of study and scholarly as well as Presidential condemnations. People will have to refuse their participation since they still have no legal protection against getting deceived about the risks involved for them, just as the victims of the U.S. *Health Service* in the *Tuskegee Study* were lied to. For subjects whom doctors are trying to lure into their fraudulent experiments, as they did in Tuskegee, refusing to participate is the only rational reaction.

This refusal of people to be duped is bound to cause setbacks for some maybe legitimate and maybe even potentially beneficial medical research. However, those expected setbacks are the direct result of the medical deceptions and of defending those deceptions.

The fraud in SUPPORT was glaringly evident and is well documented. On July 11, 2013, a self-described "group of physicians, bioethicists, and scholars in allied fields" agreed with the *OHRP* and itemized that the consent forms for the SUPPORT experiment failed in each of the elements required by the U.S. *Federal Regulations*. The 45 signers of this criticism explained clearly that the oxygen interventions for the two groups in that experiment had been different from standard care, and that the potential difference in the risks was "reasonably foreseeable since determining differential risk was the very purpose of the study." <sup>37</sup>

However, the proponents of that questionable SUPPORT experiment tried to gloss over those differences in risk. They falsely represented the researchers' intervention as just the same care the subjects would have received anyway even if they had not been enrolled in the experimental treatment groups. Their unashamedly bogus claim that there was no difference in risk is yet another blatant lie unworthy of people who pretend to be scientists. This lie contradicts the very purpose of the experiment as well as the researchers' explicit statements about their goals which were to compare those now allegedly non-existent risks, and it destroys any scientific credibility these defenders may have had. No one can trust anything said by a person who lies so impudently about matters of life and death.<sup>38</sup>

Yet, in response to Judge Bowdre's recent *Opinion*, some defenders of the SUPPORT ethics violations recycled again their old and already long debunked assertions that the experiment had been conducted ethically, as cited in the September 10, 2015, article "UAB study probably did not cause injuries to premature babies, judge rules" by Amy Yurkanin at al.com:

"Editors at the New England Journal of Medicine have supported UAB, its institutional review board and Carlo throughout the controversy.

"This system of oversight worked well," wrote Dr. John D. Lantos in a commentary for the *New England Journal of Medicine*. "It protected the rights and interests of research participants. It allowed an important study to be conducted with the highest ethical standards. And it allowed the research to answer an important question about the best way to care for premature infants. The summary judgment is thus a vindication of both the investigators and the U.S. system of research oversight. There is no reason to fix a system that is not broken."<sup>39</sup>

These comments had already been shown at the *OHRP*'s public hearing to be baseless and wrong, and their mindless repetition in response to Judge Bowdre's *Opinion* simply show that Dr. Jeffrey M. Drazen, the editor of the *NEJM*, and the "bioethicist" Dr. John D. Lantos as well as the other defenders of the SUPPORT experiment have no clue about ethics, medical or actual. Their inability to accept evidence and their brazen lying about it disqualifies them in this discussion since they merely regurgitate their guild-protecting fact-free talking points. They also claim that the research had answered an important question although it offered no such answer, and the dilemma about any ideal oxygen level for premature babies remains just as unsettled as it was before this \$20-million-wasting experiment that deliberately killed 23 babies for nothing.

But then, dishonesty is an inherent trait for the SUPPORT researchers and their defenders. Earlier and in a more general context, Dr. Lantos had even openly advocated lying to patients as part of normal medical practice:

"In medicine, of course, there is a long and distinguished tradition of lying. (...) The age-old medical adage to do no harm has become essentially obsolete in modern medicine. We do harm all the time, generally in hope of achieving a greater good. (...) As with most modern bioethical paradigms, all bets are off when it comes to pediatrics. (...) Sometimes, perhaps, even in America, the best medicine might still be a comforting lie." <sup>40</sup>

The idea that physicians are allowed to lie "for a greater good" invites the sort of hubris that justifies deception for purposes which only the medical *Übermensch* can evaluate. It allows these would-be superior judges to disregard their unctuously proclaimed *Declarations of Medical Ethics* and to ignore the horrible lessons that had led to their modern model, the *Nuremberg Code*. By so disdaining the essential requirement of informed consent, Dr. Drazen and Dr. Lantos *et al.* undermine any potential research subjects' confidence in that protection which would be required for the future of any medical research on humans. They also confirm that the formerly reputable *NEJM* has become a mere parroting mouthpiece for the huge clinical research industry which now operates above the law.

Merely debunking this fact-proof and arrogant mindset is not enough to end these medical crimes. The rule-violating researchers have to face penalties for the harm they cause with their stubborn behavior. In a 2001 editorial titled "*Tuskegee: Could it happen again?*", Professor Susan M. Reverby, the Wellesley historian of American health care and expert on the *Tuskegee Study* who re-

discovered in 2010 the existence of the 1946 to 1948 US syphilis study in Guatemala, had warned that

"Moral statements from international medical bodies, overworked governmental regulators, and quickie courses on ethics in our health science schools and for continuing education credit may no longer be enough to protect us from the modern-day equivalents of what happened in Tuskegee. (...) We need serious sanctions against those who violate these new rules and principles. (...) Without our commitment to such elemental justice, the next Tuskegee is surely now being planned."<sup>41</sup>

Her 2001 warning was earily prescient for the SUPPORT study and its international NeOProM siblings which were conceived about two years after her editorial predicted them.

On the other hand, the free pass that the evidence-disdaining and law-bending Alabama Judge Bowdre gave to the defendants in the complaint against the SUPPORT abuses virtually guarantees that crimes like those in the Tuskegee study and the SUPPORT experiment will continue to be repeated again and again.

# 4.) "Truthiness" in the pediatric doctrine

"Truthiness" is a word coined in 2005 by the TV-show host Stephen Colbert that became Merriam-Webster's "Word of the Year" for 2006. He defined it as "The quality by which one purports to know something emotionally or instinctively, without regard to evidence or intellectual examination" and added "The truthiness is whatever I want it to be."

This truthiness concept explains how the "Background" section in Judge Bowdre's Opinion could contain the grossly inaccurate statement about the peripheral capillary oxygen saturation levels (SpO<sub>2</sub>) measured by pulse oximeters in the blood of premature babies:

"... extremely low levels (below 70 %) could result in death or neurodevelopmental impairment ..."

This exaggerated low-balling of the alleged fatality limit is based on a reckless distortion of the dangerous oxygen saturation levels by some highly placed unconditional defenders of the SUPPORT experiment who wanted to make the 85 to 89% levels in the low-oxygen group of that suffocation experiment appear safer than they actually are.

The Director of the U.S. *National Institutes of Health* (NIH), Dr. Francis Collins, and two of his top executives there, the Deputy Director for *Science, Outreach, and Policy*, and the Director of the *National Institute of Child Health and Human Development*, saw nothing wrong with the SUPPORT researchers' knowingly asphyxiating 23 human babies for "medical science". Even worse, they deliberately and dangerously misrepresented the clinical literature in their attempt to cover up this criminal violation.

Lying about the risks from medical experiments is clearly still the default option for the *U.S. Health Service* even though it has been renamed to become the *National Institutes of Health*.

These current NIH leaders claimed in a June 5 paper that restricting the range of oxygen levels in two groups at 85 to 89 and 91 to 95 percent was the equivalent of the "standard of care" which recommended the full range of 85 to 95 percent. They said that there was no difference in risk between the groups although the experiment was conducted specifically to compare that now allegedly non-existing difference. Compounding that lie, they further pretended that the "extra" deaths of the victims in the low-oxygen group had been "unexpected" and that there had been "no basis for claiming an increase in risk" in the oxygen-starved group. They also denied any obligation of telling the parents about the lopsided trade-off in harm the SUPPORT researchers were testing on their children. Their distortions of the facts are most dangerous when they claim that

"The more recent studies showed no increased risk of death or neurodevelopmental impairment at saturation levels as low as 70 percent."<sup>42</sup>

Either these top U.S. Health officials cannot read a clinical paper, or else they know they are willfully spreading potentially lethal misinformation to support their lie. The one study they cherry-picked to represent those alleged "recent studies" included a group with a nominal oxygen saturation range of 70 to 90 percent, but its authors had explained clearly that this was not the actual saturation:

"Staff always aimed to maintain saturation in the top half of the target range (particularly when the lower limit of this range was less than 85%). No formal attempt was made to document how often saturation fell outside the recommended management limits, but review of a random sample of case notes quickly showed that narrowly set limits were broached much more often than wider limits, and that staff occasionally responded in this situation by "muting" the saturation alarm altogether." <sup>43</sup>

Another major difference between the groups was that all of those in the high-oxygen group, with 88 to 98 percent saturation, had an arterial line inserted for regularly making sure the arterial blood saturation stayed below the upper target limit. By contrast, only four out of the 65 babies in the low-oxygen group had that tube inserted to keep them from exceeding their upper limit. In other words, they could have spent much time with oxygen levels even above their nominal 90 percent limit, particularly when the alarms were muted. Despite the low nominal 70 percent bottom of that theoretical range, the babies assigned to that group were therefore unlikely to ever have been anywhere near that alleged 70 percent saturation for any length of time.

Moreover, three of the SUPPORT researchers, including the defendant Dr. Carlo, had written in a September 23, 2010, letter to the editor at the *NEJM*:

"Experts have recommended the use of oxygen saturation targets below the lowest level used in our trial (85%) on the basis of results from nonrandomized studies. Oxygen saturation

levels below the low targets increased as clinicians aimed for these targets4. Our preliminary unadjusted analysis indicates that **infants who died spent a higher proportion of time** (P<0.001) with saturations below 80%.<sup>44</sup> (emphasis added)

In other words, the researchers were apparently so unconcerned about the safety of their subjects that out of curiosity they seem to have exposed some of them to oxygen levels even lower (and even more dangerous) than the lowest stated target range of the SUPPORT protocol, and the authors of that letter found that saturations below 80 percent were highly likely to be associated with death, with a 99.9% probability.

Yet, three top officials at the *NIH* recklessly and falsely pretend that the danger level begins only below 70 percent. They clumsily try to obfuscate the well-known and widely documented mortality risks from restricting oxygen to preemies, and to cover up the SUPPORT researchers' irresponsibility of having exposed hundreds of children to this danger. This concealed increase in risk killed 23 of the preemies and left a still unknown number among them with severe and permanent brain damage, courtesy of the SUPPORT researchers who failed to tell the parents anything about those risks.

The fact that an alleged lower safety limit of 70% is cited in the Court document which is supposedly based on the sworn testimony of the defendants, including Dr. Carlo who had previously written that even 80 percent was highly fatal, suggests that the defendants escalated the distortions of the NIH officials to an even more devious escalation of truthiness which one may have to call "oathiness", for the willingness to assert their knowingly wrong made-up factoids under oath.

This incident also offers you a glimpse at how flimsy the foundations are for a pediatric doctrine and pseudo-scholarship that uncritically accepts such blatant misrepresentations of the literature by medical authorities and then repeats them even under oath. Today's unconditional defenders of the SUPPORT ethics violations and outright preemie-killing crimes still display the same unshakeable but baseless convictions which the French playwright Molière derided in 1673 as part of the medical mindset:

"He's a doctor through and through, a man with more faith in his rules than anything capable of mathematical proof. He would think it a crime to even question them. Medicine has no obscurities for him, no doubts, no difficulties. Full of headlong prejudice, unshakable self-confidence, and no more common sense and reasoning than a brute beast he goes on his way purging and bleeding at random and hesitates at nothing. It's no good bearing him ill will for the harm that he does you -- he'll send you into the next world with the best of intentions and in killing you off do no more for you than he would do for his own wife and children or, if need arose, for himself."<sup>45</sup>

Of course, most of today's doctors will try to convince us that this portrait of a typical doctor dates from the pre-scientific days of medicine, and that modern medical knowledge is much better founded. Unfortunately, upon inspection this claim turns out to be as much of a Potemkin façade as the similarly touted *Codes* of medical ethics.

The emptiness behind this façade was most spectacularly exposed by Dr. John P. A. Ioannidis. He is currently a Professor of Medicine and of Health Research Policy at *Stanford University* and Director of the *Stanford Prevention Research Center* at the *School of Medicine*, and he has a long list of other prestigious appointments as well as editorships and awards to his name. He is also one of the most-cited scientists worldwide<sup>46</sup>. *The Atlantic* monthly magazine selected Dr. Ioannidis as the Brave Thinker scientist for 2010, claiming that he "may be one of the most influential scientists alive".<sup>47</sup>

Some of this enthusiastic acclaim is due to his eye-opening series of papers about the flaws in medical research which starts with his *PLoS Medicine* article titled "Why most Published Research Findings are False" which has been the most-accessed article in the history of *Public Library of Science* (1.4 million hits) and is now also posted on the website of the *National Institutes of Health*<sup>48</sup>.

In this meticulously researched and documented paper, Dr. Ioannidis offered a series of reasons why most medical research findings turn out to be false. These include that there may be no true relationship between the elements compared, that the study design and/or analysis may be wrong, or that financial interests or prejudice may have influenced the study outcomes. He also showed that claimed research findings may often be simply accurate measures of the prevailing bias, and he demonstrated that for most study designs and settings, it is more likely for a research claim to be false than true.

Some of these reasons, such as financial interests, prejudice, and prevailing bias have clearly contributed to the consistent wrongness of most research about ROP which has more than its fair share of bogus results. He also cited the serious problem of outright fraud which confidential surveys showed to be much more widespread than scientists like to acknowledge<sup>49</sup>. In the case of ROP, this problem has dominated the research and steered the entire ROP-field in a wrong direction. It began in the 1950s with the deliberate fraud of the initial researchers who contrived, driven by their eugenicist agenda, to fabricate a non-existing relationship between the baby-blinding and the oxygen breathing help. This could never be replicated but led doctors to uncritically accept oxygen as the culprit for the blinding although in fact it only enhances the eye damage caused by the fluorescent nursery lighting and had never caused any ROP before the introduction of those lamps. The next major research fraud about ROP was the underhanded rigging of a clinical trial in the 1990s to falsely deny the undeniable relationship between the epidemic of that blinding and the eye-damaging *blue-light-hazard* component of the fluorescent nursery lighting specified by the *American Academy of Pediatrics*.

An examination of these fully documented research frauds shows that there are no honest foundations whatsoever for the entire medical campaign against the much needed oxygen breathing help for premature babies, nor for the falsely alleged safety of the nursery lighting. Although many

medical researchers have invested much of their careers in those wrong but unshakeable assumptions, it turns out that the absolute faith of today's nursery doctors in their fraud-based doctrine is as misplaced as that of Molière's doctors in their earlier and just as patient-harming quackery.

#### 5.) The start of the alleged link between oxygen and baby-blinding

The first babies ever to suffer from ROP were born in Boston in 1940. By then, nursery doctors had administered oxygen supplements to premature babies routinely and generously for many decades without ever causing any eye damage<sup>50</sup>. Although some current writers on ROP try to cook up scenarios of a change in oxygen practices at that time, these are transparent *ad hoc* inventions to retroactively explain the blaming of oxygen – another example of truthiness in neonatology. There neither was nor is any rational reason to link the then new and quickly spreading epidemic form of baby-blinding to this long established and consistently life-saving oxygen breathing help, and all attempts to confirm this allegation have turned out questionable.

However, blindness had been a favorite target of U.S. eugenicists<sup>51</sup>. Their pseudo-science dominated medical thinking during the first half of the 20<sup>th</sup> century to the point that 31 U.S. states enacted medically inspired sterilization laws to keep "undesirables" from contaminating the gene pool. And some of the most influential American ophthalmologists at the time believed that ROP was caused by "defective germ plasm".

One of these was Dr. Algernon B. Reese, President of the *American Academy of Ophthalmology and Otolaryngology* and editor of its "*Transactions*" journal. He came from the *Harvard Medical School* which was a bastion of the eugenics movement and had been a major driver for the eugenic sterilization laws in the U.S. That *School* had also supplied some of the architects for the eugenics program in Nazi Germany as well as highly publicized "scientific" support for Hitler's racial policies <sup>52</sup>. In 1928, the *Harvard Medical School* founded the *Howe Laboratory of Ophthalmology* as a joint venture with *Mass Eye and Ear* to promote ophthalmic research and education with a major emphasis on ophthalmic genetics. It was named after Dr. Lucien Howe who was a celebrated ophthalmologist and president of the *American Ophthalmologic Society* as well as the president of the *Eugenics Research Association*. This ardent eugenicist had made blindness his major target as a model case for the eugenic sterilization laws he zealously promoted. He even was determined to "hunt down" anyone with vision problems as well as their relatives and to imprison them as "protection against future defectives" <sup>53</sup>.

Primed by this eugenicist background at his highly regarded Alma Mater, Reese wrote several learned-looking papers about the new eye damage to assert its allegedly prenatal origin caused by "defective germ plasm". He presented the latest of these at the June 23, 1948, meeting of the *American Medical Association*'s *Section on Ophthalmology* where he and his like-minded colleagues recommended that the best way to deal with the epidemic was to "not be so zealous in preserving defective persons, of which the world has a sufficient quantity already". <sup>54</sup>

The most effective way to preserve the lives of premature babies was and is to help their still immature lungs with supplemental oxygen. As mentioned above, oxygen had by then been given routinely and generously to premature babies for several decades and was highly acclaimed as a "life-saver", without ever having caused any eye damage.

Letting supposedly "impaired" babies die without life-saving treatment had long been a tacitly accepted and at times even openly promoted custom since the beginning of the century<sup>55</sup>. Even the Bishop of Baltimore had supported this practice in the Catholic Review of November 19, 1915<sup>56</sup>. However, in those postwar years of Reese's presentation, the American public had newly learned about the horrors the Nazis had committed in the name of eugenics, including their brutal mass euthanasia programs against disabled people as "useless eaters". Given this reversal in the reputation of eugenics, there was no way any American doctors could openly carry out a similar action against "preserving defective persons" by withholding their oxygen breathing help. However, they could and did disguise that agenda with their usual habit of lying.

Accordingly, this group of doctors and some of their British colleagues began a smear campaign against oxygen as an "undeserved subsidy" that stifled the infants' "private enterprise" of breathing on their own<sup>57</sup>. They also ran some small-scale experiments to discredit its benefits but conspicuously omitted to report the critical mortality rates<sup>58</sup>. Then the group around Reese launched in 1953 the multi-hospital *Cooperative Study of Retrolental Fibroplasia* (as ROP was then called) to more convincingly blame the blinding on that oxygen breathing help<sup>59</sup>.

That *Study* was an evident research fraud. Its designers had never changed their conviction that the damage was a prenatal genetic "defect" and could therefore not be caused by anything done to the babies after their birth. Yet, they withheld the oxygen from virtually all babies for the first two days and then only enrolled the survivors of this merciless weeding in their study. By that time, 45 percent of the babies had died<sup>60</sup>, as compared, for instance, with 32 percent of similar babies who had died in the first seven days in one of the study hospitals during the immediately preceding two years<sup>61</sup>.

However, the designers of this *Cooperative Study* concealed this better-dead-than-blind carnage and deceptively claimed that they had practically wiped out the blinding without affecting the survival rate. Instead, they had covertly killed the babies who would otherwise have grown up blind. Their apparent victory against the epidemic was greatly hailed as a triumph of the then still relatively new concept of double-blind randomized studies, and it led the U.S. Congress to greatly expand the funding for this kind of medical research.

The authoritative propaganda about this alleged triumph and the welcome prevention message against a baffling epidemic instantly led nursery doctors around the world to severely restrict the breathing help for all premature babies. This started the systematic but undisclosed eugenics-based euthanasia program the study designers had intended with their recommendation to "not preserve the defective persons". Many of the rank-and-file doctors may have been duped by the scientific-

sounding announcement of this indictment against oxygen, but at least some of them must have known that this gas could not suddenly have become the culprit after so many decades of life-saving without ever blinding a single baby. Still, even these doubters appear to have tacitly accepted the eugenic goal of eliminating the "defective germ plasm", and they all went along with the officially proclaimed convenient solution to the blinding epidemic.

These followers even included the nursery doctors in all the many religious hospitals. They would normally have objected to this huge slaughter of the innocents which dwarfed even the massacre of babies and toddlers ascribed to the Biblical villain king Herod, but the alluring power of the eugenic promise and the authority-obeying group-think habit of their profession seems to have overridden their consciences.

I have tried over the last quarter century to alert many so-called pro-life groups to the ongoing eugenics-inspired mass-killing of premature babies but received no meaningful responses at all. It turns out that despite their sanctimonious rhetoric about protecting all life, they limit their efforts to caring only for fetuses who are still in the womb, and they are totally unconcerned about what happens to these once they are born. Even the ethics-oriented online Catholic newsletters *Bioedge* and *Mercatornet*, which protested against recent "bioethicist" proposals to end the lives of newborns with disabilities that made them "not worth living", declined to speak up against the systematic preemie-suffocation when I repeatedly sent them evidence about this actual ongoing eugenicist program of hidden mass euthanasia.

Many of those who loudly claim to be "pro-life" in the defense of embryos are totally indifferent towards the medical mass-asphyxiation of already born and mostly viable premature babies, or towards the premeditated killing of 23 "extra" children for medical research in the ill-conceived SUPPORT experiment. Their lack of concern about these ongoing abuses contrasts starkly with the recent uproar in the U.S. Congress when some of its members threatened to shut down the government after they saw deceptive videos about the long-standing and legal practice of medical researchers to obtain fetal tissues from abortions by *Planned Parenthood*. They displayed a mindless gut reaction to the legitimate use of dead aborted tissues for potentially life-saving research on fetal stem cells for treating diabetes and many other conditions, as well as for drug testing and for some vaccines. Their preference for incinerating these useful tissues instead as medical waste highlights their hypocrisy of condoning the industrial-scale clinical killing of live and wanted babies without even lifting a finger to stop this actual crime.

The medical reaction to the eugenically motivated eliminating of "weakling" premature babies is consistent with the continuing eugenicist features of the profession's "macho" culture which appears to be stuck in a time warp. The current medical curriculum still subjects its aspiring resident doctors to unnecessary but grueling "survival of the fittest" endurance tests that routinely require work weeks of 100 to 120 hours with individual shifts of 24 or more consecutive hours. Those conditions impair the judgment of the sleep-deprived care providers and often result in severe harm to patients. This brutal indoctrination also drives up the suicide rate among its victims, and it dehumanizes many

of its survivors to the point where they lose the initial idealism that drove them towards a medical career. Instead, they become compliant cogs in a secretive and arrogant system that is designed to assure the power and wagon-circling impunity of the medical profession instead of the quality or suitability of the care it provides<sup>62</sup>.

A nurse said fittingly in an online forum post about the medical community's mistreatment of its residents: "They eat their own young".

Some nursery doctors also appear to reveal the same aggressive attitude towards premature babies. The withholding of sufficient oxygen is a torture even worse than the notorious waterboarding. To get an idea how this almost-suffocation must feel to a baby, compare, for instance, the account of the adult *Biosphere* 2 volunteers who became sluggish, weak, sore and depressed when the oxygen levels in their sealed enclosure dropped just a little, and who felt profound relief when they could again breathe oxygen-enriched air<sup>63</sup>. The babies' pain is likely to be even greater than the sensation of imminent asphyxiation experienced by subjects of waterboarding which is hard to tolerate even for robust adults. That adult torture is usually stopped before the victim suffers permanent damage, but the preemies have to endure their protracted deprivation for hours or even days and weeks without any relief, to the point that many of them suffer life-long brain injuries or even die from the ordeal.

Moreover, the tech-oriented factory-like nursery environment inflicts on the babies also much of the sensory overload with loud noises and overly bright light, and the resulting continuous sleep deprivation, that the CIA is accused of having used against its torture victims.

Already the Ancient Roman medical writer Celsus [c. 25 BCE – c. 50 CE] recommended that newborn babies should be protected from loud noises and bright light, and baby-friendly parents before and after him have long instinctively practiced these protections. However, this commonsense advice appears to be lost on modern nursery doctors. Their idea of a proper environment for babies appears to be designed to make these sicker than they already are and to deny them the rest they need for healing so that they will have to spend as much time as possible in the intensive care nursery which is in many hospitals their most profitable department.

So far, there has been no investigation of this vast crypto-eugenicist research fraud and crime of systematic baby-suffocation, like those conducted for the much smaller-scale unethical syphilis studies in Guatemala and Tuskegee, or the equally infamous *Human Radiation Experiments*. Although some of that oxygen-withholding carnage is well documented, and even the commonly cited low-balling medical estimate says it killed 150,000 babies in its first two decades, no one has held the medical community accountable for this massive slaying and maining and hurting which cannot be explained away as mere error or ignorance.

This cited number of victims is the equivalent of a jumbo-jet crashing every three weeks and each time killing all its about 440 passengers. If this had happened in actual air travel, professional investigators from the *Federal Aviation Administration* would right away have analyzed every scrap

of evidence and come up with solutions, from discovering esoteric phenomena like the metal fatigue that downed the early Comet jets to developing checklists for reducing pilot errors, and they would surely have lessened the slaughter very soon.

However, although medical doctors claim to be professionals, none of them launched any comparable sleuthing effort to find the clues for their clearly iatrogenic carnage. They kept barking up the wrong tree with their consistently ill-conceived oxygen withholding experiments that amount to nothing more, in this comparison, than checking only the influence of local gravity variations on the incidence of the crashes. Beyond that, they simply accepted the massacre, particularly since it suits the hidden aims of their eugenicist culture, and they stopped counting the continuing toll from their "survival of the fittest" policy since it is easier to hide those deaths than to openly examine them.

For instance, in the most recent of many pointless asphyxiation experiments, the SUPPORT researchers ignored their guild's traditionally advertised motto of "first do no harm" and thereby predictably killed 23 human babies with their suffocation research. Then they announced their improvement over the initially reported 16 deaths per case of blindness prevented from the beginnings of oxygen withholding:

"Our data suggest that there is one additional death for approximately every two cases of severe retinopathy that are prevented." 64

Since death and blindness have greatly different values, particularly to those directly affected, the SUPPORT researchers' deal changes from the equivalent of paying 16 dollars to save one penny to paying only one dollar for saving two pennies. This may be an improvement, but it remains an unacceptably bad trade, and none of the SUPPORT and other NeOProM researchers have any right to strike such a lopsided deal on behalf of anyone in their care, nor do any parents have a right to knowingly volunteer their baby for such a risk without a matching reward. Ask any non-suicidal blind person whether they would prefer to be dead than merely blind, and their answer will expose the lopsided value misjudgment of these researchers.

However, the typical headlines following the release of the SUPPORT results were of the "hosiannah" type, such as Dr. Waldemar Carlo's "*UAB Study shows Lowering Oxygen Level for Preemies Lessens Severe Eye Damage*", published on May 16, 2010, by the *University of Alabama Birmingham* School of Medicine's Department of Pediatrics. Dr. Carlo, the leader of this nationwide experiment, announced there proudly but incorrectly that

"... none of the previous studies have looked at the range of oxygen saturation sufficient to minimize ROP without increasing adverse outcomes, including neonatal mortality."

Only towards the end of the article does he concede that this touted prevention of ROP also, just like many of the previous studies,

"... increased the chance a neonate would die before discharge".

Moreover, Dr. Carlo's conclusion left it again up to the individual doctors' opinion how much weight to assign to each of those different outcomes, without any new or useful guidance gained from this costly experiment that ruthlessly sacrificed the lives of 23 "extra" babies to medical research with no constructive result:

"Health care providers should try to prevent both too high and too low levels of oxygen saturation to optimize survival without retinopathy." 65

The leader of this study leaves this undefined optimal level up to the reader, as if the current rules and regulations were not unanimously clear about not risking death to prevent a lesser problem.

Contrary to those rules, the medical community's reaction to these non-results from the SUPPORT experiment reflected the resurgence of open "eliminate-the-weaklings" eugenics. A little over a year after its publication, on August 6, 2011, the *San Luis Obispo News* quoted the Medical Director of the local *NICU* as saying that

"... newer guidelines just coming out lower the amount of oxygen given to preemies even further."

Not being on the *American Academy of Pediatrics*' mailing list, I was unable to find a copy of those "newer guidelines", but an article by Laura Landro in the *Wall Street Journal* of July 19, 2011, described a situation apparently also based on them:

"Some neonatal intensive care units are cutting back on the high levels of oxygen traditionally given to premature babies. (...) Nurses used to be taught that babies should have a blood oxygen saturation level of 99 per cent and appear glowing pink and healthy", Ms. Rikli says. 'It was hard for some nurses to accept reducing blood oxygen levels to the 85 per cent range, despite research linking higher levels to blindness. It takes constant vigilance and persistence to show nurses the data and to hold them accountable,' she says."

The advocates of tighter restrictions on breathing help omit to say that the medical experiment behind these new guidelines for lower oxygen levels had killed 23 "extra" babies in the low-oxygen group, and that the *SUPPORT* researchers had announced as their result, as quoted above, that they had caused one additional death for approximately every two cases of severe ROP prevented.

There is no version of real ethics that would consider such a skewed trade-off acceptable, but those alleged "newer guidelines" based on the illegal SUPPORT experiment advised nursery doctors that it is better to kill preemies than to let them grow up blind, confirming the widespread medical attitude of "better dead than living blind".

Actually, this may match the narrow and cynical perspective of some doctors because parents are less likely to sue their baby's doctor over that baby's death than over his or her blindness. It may

therefore be in the doctors' interest to just kill off the most vulnerable babies, just as they have been doing for the past sixty years, based on crooked research and intentionally baby-killing eugenics-influenced guidelines.

After these initial reactions, there has been more medical debate about the lessons to draw from the SUPPORT experiment. However, that debate remains inconclusive, and the euthanasia method of suffocating babies to keep them from growing up blind has not been repudiated. This very fact shows the continuing powerful influence of eugenic thinking in modern medicine, both in the U.S. and also in other countries that follow the oxygen restriction doctrine introduced some 60 years ago by American eugenicists.

It is time to introduce real ethics and common sense instead of the eugenics-tainted "bioethics" into this now evidence-disdaining and patient-harming approach to treating premature babies. Unfortunately, the leaders of the medical establishment don't stop circling their wagons to defend their entrenched practice instead of at long last admitting the ongoing mass asphyxiation.

That bogus *Cooperative Study's* openly biased verdict against life-saving oxygen is now an unshakable cornerstone of the intensive care nursery industry's theory and practice although it blatantly disregarded all previous evidence and decades of experience, and it accepted a single new contradictory asserted finding without any evaluation. This indictment of oxygen also could never be duplicated or confirmed despite many later attempts to do so. And yet, its fake and deceptive recommendation for large-scale euthanasia through oxygen rationing still affects the daily life in intensive care nurseries and for parents around the world probably more than any other single study ever did.

Oxygen management has also been said to account for about 30 percent of all the costs and billings in a typical intensive care nursery, so the profits from this baby-harming routine may further help to explain the persistence of this unscientific practice.

# 6.) Medical denials that the blinding is caused by the excessive nursery lighting

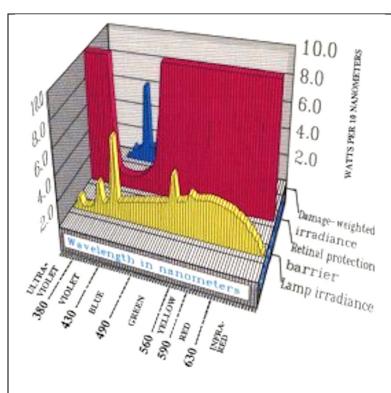
Besides killing 23 human subjects for their callous research and concealing that well-known risk from the parents, the SUPPORT researchers also ignored their obligation to base their experiment on a thorough knowledge of the scientific background and a careful assessment of the risks and benefits, as required by the *Nuremberg Code* and the *Helsinki Declarations of Medical Ethics for Human Experimentation*.

The SUPPORT researchers claimed their goal was to prevent or reduce the blinding of the infants from ROP which they unquestioningly assumed, against all historical evidence, to be caused by excess oxygen. However, as documented above, oxygen had by then been given generously for many decades without ever having caused any case of ROP or other eye damage. On the other hand, already the discoverer of ROP had written early-on that the most logical cause for this damage to the most light-sensitive organ was the babies' premature exposure to light. Although he did not yet

connect all the dots, his reasoning was right because the ROP epidemic had started in the U.S. the year after the commercial introduction of fluorescent lamps, and the same parallel repeated itself after World War 2 in other industrial countries as those lamps became available there and the ROP epidemic broke out just as suddenly in their wake<sup>66</sup>.

Reese and a few other doctors had pretended to test the effect of light during their campaign of blaming oxygen, but they all patched the eyes of the allegedly protected infants only up to 24 hours after birth<sup>67</sup>. They knew that thermal eye damage from intense light, such as staring at the sun or at a welding arc, accumulates within a few seconds. As ophthalmologists, they should also have known from the analogy with photographic film that lesser intensities act slower but cause the same result with just slightly longer exposure times. The formal quantification of this photochemical process in retinal tissues would be confirmed only several years later, but the principle was already evident from the beginnings of photography.

Systematic research from the 1960s on to prevent eye damage from industrial lasers showed indeed that bright light inflicted its latent eye damage typically in a matter of minutes, not multiple hours or even days. These industrial-safety researchers also established that the most retina-damaging light is in the "blue-light-hazard" wavelength region from 430 to 440 nanometers. And it just so happens that virtually all fluorescent lamps, including those specified by the *American Academy of Pediatrics* for intensive care nurseries, emit a major part of their energy precisely in the middle of that most dangerous range, at 435.8 nm.





## Fluorescent spectrum

The yellow curve shows the spectrum emitted by the Deluxe Cool White lamp from Sylvania which is similar to that from other makers of the same model. The horizontal axis gives the wavelength in nanometers and the vertical axis the intensity of the irradiation in Watts per ten nanometers. The tallest spike is at 435.8 nanometer in all fluorescent lamps. It is actually higher than shown on this graph which averages the energies over bands 10 nm wide. This wavelength is right in the middle of the area of greatest vulnerability to blue-light damage for all mammalian retinae which ranges from about 430 to 440 nanometers and is here represented by the gap in the red "retinal protection barrier".

(Graph by the author: Bluelightbarrier.tif)

Blinding preemies with nursery lamps

The eyes of this premature baby are patched to protect them from the bright fluorescent lamps used to reduce the bilirubin level in his bloodstream. These bilirubin lamps are only three to five times brighter than the typical intensive care nursery lighting to which the babies' unprotected retinae are exposed 24 hours a day. They are well-known to cause eye damage, but the only slightly less intense regular ceiling lamps are somehow deemed safe, without any evidence.

(Image: EyePatchedPreemie02.tif, photo by author)

Adult eyes are somewhat protected from that hazard because our lens and vitreous become yellow as they age and so do not let all this blue-violet penetrate to the retina. By contrast, the eyes of babies are still very transparent and lack this protection, and those of preemies are even more vulnerable because their retinal vessels are still developing and are therefore extremely sensitive to any irradiation during this stage. Yet, the typical intensive care nursery lighting of 60 to 100 foot-candles exposes their retinae in less than 15 minutes to the amount of damage-weighted retinal irradiance that the U.S. *Industrial Safety Guidelines* have established as the danger limit for adult workers over an eight-hour shift<sup>68</sup>.

The presence of oxygen enhances the radiation damage caused by the blue-light-hazard, but oxygen alone does not create that damage. The history of ROP shows clearly that without the exposure to blue light, supplemental oxygen alone, even in generous concentrations, never caused ROP or any other eye damage.

To test the role of light in ROP, regardless of wavelength, researchers in three D.C. area hospitals covered in 1982 all the baby incubators with gray filters to reduce the irradiation of the babies from 60 foot-candles to 25 ftc. This drastically reduced the incidence as well as severity of ROP in all the birth weight groups, with a chance of only one in a hundred for the smallest babies that this might be a fluke. However, some doctors commenting in the *NEJM* quibbled that this study was of the before-and-after type, and this gave them a pretext to reject these embarrassing and liability-threatening findings<sup>69</sup>. They omitted to note that the 1955 fraudulent oxygen study had also been mostly of the before-and-after type but instantly became the unquestioned neonatology doctrine despite a lack of any replication.

This flimsy excuse to ignore the nursery lights did not convince the public, so two pediatric retinal surgeons rigged in the 1990s the bogus LIGHT-ROP experiment to silence the critics of the nursery lighting with the *ex cathedra* clout of a multi-hospital medical study. Although many of the references these surgeons cited in their grant application and study protocol described light damage from quite short exposures, including my above-cited quantification of danger limits from the *Industrial Safety Guidelines*, they again delayed the eye patching in their allegedly protected groups for up to 24 hours. As a result of the researchers' so defeating the alleged purpose of their study, both groups had the same incidence of ROP, and this trick falsely "proved" the innocence of the fluorescent lamps<sup>70</sup>. Their deliberately deceptive result is now enshrined on the NIH website as the reigning dogma:

"Although it had been suggested as a factor in the development of ROP, researchers supported by the National Eye Institute determined that lighting levels in hospital nurseries has [sic] no effect on the development of ROP.<sup>71</sup>

This knowingly wrong information helps to prolong the profitable ROP epidemic which provides a steady stream of captive customers for pediatric retinal surgery, and it shields the nursery doctors from any accountability for the continued baby-blinding epidemic.

Denying the damage done by the nursery lights also helps to drive other businesses such as, for instance, the supply and maintenance of oximeters for monitoring the arterial oxygen levels of all premature babies although it has been known since 1924 that the retinal oxygen levels are independent of those in the peripheral vessels which the oximeters measure instead<sup>72</sup>. This irrelevant non-retinal oxygen control is one of the major activities and profit generators in a typical intensive care nursery where one third of the expenses, itemized as Ventilation and Oxygen Administration, goes typically for oxygen management and measuring.

Providing those oximeters is so profitable that their major manufacturer, Masimo Corporation, paid more than \$930,000 in just the last five months of 2013 to selected doctors as consulting fees, travel costs, and gifts to promote their equipment, including \$60K to the editor-in-chief of the journal Pulse Oximetry<sup>73</sup>. But instead of warning about the very real risk of death from oxygen rationing which the SUPPORT experiment had again reconfirmed, the Masimo press release about it crowed instead

"New Multi-Center Study Finds Clinical Practice Change with Masimo SET Pulse Oximetry Reduces Severe Eye Damage More Than 50% in Premature Newborns"<sup>74</sup>.

They simply and irresponsibly chose to ignore the "extra" deaths caused by the use of their equipment.

Other areas of ROP-related profits are regularly touted to investors in telemedicine, which allows the remote diagnosis of the eye damage from digitally generated and transmitted RetCam images, and in drug development where, as of late 2014, at least seven major pharmaceutical companies had potential therapeutic candidates in the pipeline<sup>75</sup>.

# 7.) Ending the euthanasia and ROP-blinding against premature babies

The fake LIGHT-ROP trial as well as the *Cooperative Study* oxygen swindle need to be exposed and retracted before any progress can be made to end the ROP epidemic.

Also, all babies need to be protected from the blue-light hazard of the fluorescent nursery lamps, either by coating these with a yellow filtering layer that reliably blocks the offending wavelengths, or else by replacing them with the incandescent lamps that had been used for many decades without ever causing any eye damage.

It may also be possible to replace the current nursery lighting with energy-saving LED bulbs but so far all LED emission spectra I have seen show a pronounced spike in the blue-violet region, regardless of their "color rendering index" or nominal "color temperature". That blue spike is less strong than for fluorescent lamps but must be considered unsafe for vulnerable eyes, and any LED bulbs would have to receive a yellow filter coating and to be checked for the blue-light-hazard before letting their light shine on premature babies.

Unfortunately, many nursery doctors and editors of medical journals are strongly opposed to any examination of their blatantly false and fraud-based dogmas about oxygen causing ROP and alleged

lack of eye damage from nursery lighting. They prefer to deny and cover up any evidence that the oxygen restrictions are causing death and brain damage and that bright nursery lighting harms the babies' eyes, despite the severe and permanent harm their denials continue to inflict on many premature babies.

Beginning in 1987, when I first assembled the evidence against the nursery lighting, I had sent my documentation of this harm to the journal *Pediatrics*<sup>77</sup>, to the *Journal of the American Medical Association*<sup>78</sup>, and to the *New England Journal of Medicine*<sup>79</sup>, as well as to many individual doctors and hospitals, and also to the do-nothing U.S. *Office for Research Integrity*. None of them refuted any of the evidence I presented, and none of them informed their audiences about this simple way of ending the iatrogenic baby-blinding epidemic. See also my 2/21/2012 open letter to the Editor-in-Chief of the *Nature Publishing Group* in which I pointed out the hypocrisy of *Nature* to unctuously condemn past medical abuses while covering up the clear evidence for the equally flagrant present ones<sup>80</sup>.

Similarly, in November, 2014, I submitted to *PLoS Medicine* an article about the ethics violations in the SUPPORT experiment and the role of fluorescent light in ROP. Their response illustrates the typical arrogance in the medical publishing industry that has the power to suppress any information it deems inconvenient. They replied

"we do not think that [your material] would be of the wide general interest that we are seeking for PLOS Medicine's general audience".

I pointed out that the ROP epidemic was a major cause of childhood blindness around the world and resubmitted my paper but was told that it provided "no stronger evidence for the association" with nursery lighting than my earlier cited work although that editor did not point out any weakness in my earlier argument. He simply refused to publish the unrefuted evidence against the current failed and lethal approach to the baby-blinding – see my correspondence with this fact-suppressing journal that uses the misleading slogan "Open for Discovery"<sup>81</sup>.

These consistent rejections of problem-solving evidence demonstrated clearly that the U.S. medical profession does not have a mechanism for detecting and correcting obvious errors and patient-harming flaws in its doctrine, particularly in a case like the one at hand where admitting the persistence of frauds in medical research would be embarrassing and could create potential liabilities.

The persistence of these patient-harming malpractices is aided by the medical culture of secrecy and mystery and opacity, and much of the harming could be ended by introducing transparency into the process and above all into the reporting of outcomes.

Marty Makary, MD, makes this case in an instructive Part III of his book "Unaccountable: What Hospitals Won't Tell You and How Transparency Can Revolutionize Health Care". He describes there a change in hospital cultures towards openness and teamwork, the introduction of

cameras into operating rooms, and public comparisons between hospitals for the results of certain easily defined conditions and procedures. High complication rates are profitable for hospitals as long as the patients are kept in the dark about the reasons for them, but they become an embarrassing liability and public relations problem when consumers learn about them.

Opening the outcome rates up to scrutiny quickly led to dramatic improvements in the hospitals studied, and the same is needed for intensive care nurseries. Once these have to report their numbers of deaths, ROP, deafness, brain damage, infections, necrotizing enterocolitis, patent ductus arteriosus, and similar complications so that consumers can compare them with national or regional averages for each birth-weight category, with adjustments for unusual sicknesses and information about light and noise levels as well as staffing ratios and other benchmarks, the worst-performing hospitals will have an incentive to improve their procedures and practices and they as well as their patients will benefit from these advances.

# **Endnotes:**

<sup>&</sup>lt;sup>1</sup> From the Tuskegee University's *National Center for Bioethics in Research and Health Care* Mission Statement "Ethics and Public Health", posted at <a href="http://tuskegeebioethics.org/about/ethics-and-public-health/">http://tuskegeebioethics.org/about/ethics-and-public-health/</a>

<sup>&</sup>lt;sup>2</sup> Vollmann J, Winau R.: "Informed consent in human experimentation before the Nuremberg code", BMJ. 1996 Dec 7;313(7070):1445-9, abstract posted at <a href="http://www.ncbi.nlm.nih.gov/pubmed/8973233">http://www.ncbi.nlm.nih.gov/pubmed/8973233</a>. The lead author is from the *Institute of the History of Medicine*, Free University of Berlin.

<sup>&</sup>lt;sup>3</sup> As documented by A. E. Samaan: "From a "Race of Masters" to a "Master Race" – 1948 to 1848", CreateSpace.com, 2012, see Chapter "A Conflict of Interests", page 8, citing Ulf Schmidt: "Justice at Nuremberg: Leo Alexander and the Nazi Doctors' Trial", 2004.

<sup>&</sup>lt;sup>4</sup> As posted at <a href="http://www.hhs.gov/ohrp/archive/nurcode.html">http://www.hhs.gov/ohrp/archive/nurcode.html</a>; Article 1 states: "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." (my highlighting) See also Article 5: "No experiment should be conducted, where there is an a priori reason to believe that death or disabling injury will occur."

<sup>9</sup> "Whither Nuremberg?: Medicine's Continuing Nazi Heritage" by William E. Seidelman, MD, M&GS 1995:148-157, as posted at <a href="http://www.ippnw.org/pdf/mgs/2-3-seidelman.pdf">http://www.ippnw.org/pdf/mgs/2-3-seidelman.pdf</a>, pages 4 and 5; see <a href="https://en.wikipedia.org/wiki/Hans\_Joachim\_Sewering">https://en.wikipedia.org/wiki/Hans\_Joachim\_Sewering</a> for the accusation of having killed 900 children; see also <a href="http://ahrp.org/1968-hans-joachim-sewering-appointed-honorary-professor-at-the-technical-university-of-munich/">http://ahrp.org/1968-hans-joachim-sewering-appointed-honorary-professor-at-the-technical-university-of-munich/</a>, and <a href="http://ahrp.org/1946-world-medical-association-formed/">http://ahrp.org/1946-world-medical-association-formed/</a> for other former Nazi doctors in prominent post-war medical positions; also Dr. Sewering's August 17, 2010, obituary in the British Independent at <a href="http://www.independent.co.uk/news/obituaries/doctor-hans-sewering-physician-whose-activities-under-the-nazis-caused-controversy-in-later-years-2054253.html">http://www.independent.co.uk/news/obituaries/doctor-hans-sewering-physician-whose-activities-under-the-nazis-caused-controversy-in-later-years-2054253.html</a>.

<sup>&</sup>lt;sup>5</sup> A. E. Samaan: "From a "Race of Masters" to a "Master Race" – 1948 to 1848", CreateSpace.com, 2012, see Chapter "A Conflict of Interests", pages 8 to 18.

<sup>&</sup>lt;sup>6</sup> http://large.stanford.edu/courses/2013/ph241/yeo2/ and http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1043931/pdf/medhist00027-0138.pdf

<sup>&</sup>lt;sup>7</sup> As documented at <a href="http://www.rbs2.com/humres.htm#anchor491511">http://www.rbs2.com/humres.htm#anchor491511</a>

<sup>&</sup>lt;sup>8</sup> For a more detailed list of these unethical experiments by American doctors, see <a href="https://en.wikipedia.org/wiki/Unethical human experimentation in the United States">https://en.wikipedia.org/wiki/Unethical human experimentation in the United States#Legal.2C academic and professional policy</a>

<sup>&</sup>lt;sup>10</sup> See <a href="http://www.rbs2.com/humres.htm#anchor484585">http://www.rbs2.com/humres.htm#anchor484585</a>, citing p. 190 in "Bad Blood: The Tuskegee Syphilis Experiment, New and Expanded Edition Revised Edition" by James H. Jones, Free Press, 1993

<sup>&</sup>lt;sup>11</sup> "History, Science and Medicine – The History of John Charles Cutler" by Kirk Hartley on August 30, 2011, as posted in Civil Rights at <a href="http://www.globaltort.com/2011/08/history-science-and-medicine-the-history-of-john-charles-cutler/">http://www.globaltort.com/2011/08/history-science-and-medicine-the-history-of-john-charles-cutler/</a>; see also <a href="https://en.wikipedia.org/wiki/John Charles Cutler">https://en.wikipedia.org/wiki/John Charles Cutler</a> and <a href="http://historynewsnetwork.org/article/132061">https://historynewsnetwork.org/article/132061</a>

<sup>&</sup>lt;sup>12</sup> Sarah Wickline: "Rx Risks Not Disclosed to Trial Participants: Some serious risks in boxed warnings went undisclosed in patient consent forms", Medpage Today, Public Health & Policy

# 07.28.2015, as posted at

http://www.medpagetoday.com/PublicHealthPolicy/ClinicalTrials/52813?xid=nl mpt DHE 2015-07-29&eun=g443082d0r, citing the source references Bhattacharya B, et al "Disclosure of boxed warnings to research participants" *JAMA Intern Med* 2015; DOI:

10.1001/jamainternmed.2015.3552 and Ross JS "Informed consent and communicating risk and benefits of research on higher-risk medications" *JAMA Intern Med* 2015; DOI: 10.1001/jamainternmed.2015.3555.

<sup>&</sup>lt;sup>13</sup> For a more detailed account of that LIGHT-ROP research fraud, see <a href="http://retinopathyofprematurity.org/40fraudsinLIGHTROP.htm">http://retinopathyofprematurity.org/40fraudsinLIGHTROP.htm</a> and the annotated pages from the "Manual of Procedures" for the trial protocol linked to it.

<sup>&</sup>lt;sup>14</sup> The first report about that SUPPORT experiment was published on May 16, 2010, at <a href="http://www.nejm.org/doi/full/10.1056/NEJMoa0911781">http://www.nejm.org/doi/full/10.1056/NEJMoa0911781</a>, and President Obama apologized for the Guatemala syphilis study in October of that year, but the evaluations of neurodevelopmental damage caused by the oxygen rationing in the SUPPORT experiment were still supposed to continue.

<sup>&</sup>lt;sup>15</sup> See my letters to the Chair and Vice-Chair of that *Presidential Commission for the Study of Bioethical Issues*, as posted at <a href="http://retinopathyofprematurity.org/47BioethicsOwnViolations.htm">http://retinopathyofprematurity.org/47BioethicsOwnViolations.htm</a>

<sup>&</sup>lt;sup>16</sup> For a detailed discussion of the medical resistance to obtaining informed parental consent to the risks of this experiment, which many researchers considered an expensive and unnecessary hindrance, see <a href="http://ahrp.org/babies-in-crosshairs/">http://ahrp.org/babies-in-crosshairs/</a>. These well-known and long documented risks included death and blindness and actually killed 23 "extra" babies in the low-oxygen group, but the researchers deceived the parents and hid those major risks from the consent forms.

<sup>&</sup>lt;sup>17</sup> The SUPPORT experiment was conducted in the US by the *Support Study Group of the Eunice Kennedy Shriver National Institute of Child Health and Human Development Neonatal Research Network.* It enrolled 1316 premature babies from 2005 to 2009, and its preliminary results were published in the May 16, 2010, online issue of the *New England Journal of Medicine* under the title "Target Ranges of Oxygen Saturation in Extremely Preterm Infants" at <a href="http://www.nejm.org/doi/full/10.1056/NEJMoa0911781">http://www.nejm.org/doi/full/10.1056/NEJMoa0911781</a>.

<sup>&</sup>lt;sup>18</sup> In Judge Bowdre's description of the SUPPORT trial, the oxygen levels in the two groups were 85 to 90 percent in the low-oxygen group and 90 to 95 percent in the high-oxygen group, suggesting that the defendants and/or their experts did not provide the accurate details as published in the clinical paper but made up the numbers they gave to the Judge although they were presumably under oath.

- <sup>19</sup> On May 5, 2013, *JAMA* published the paper about the nominally Canadian counterpart to the SUPPORT experiment, called COT for Canadian Oxygen Trial, at <a href="http://jama.jamanetwork.com/article.aspx?articleid=1684963">http://jama.jamanetwork.com/article.aspx?articleid=1684963</a>. This experiment had 25 participating hospitals in Canada, the U.S., Argentina, Finland, Germany, and Israel. See the second-last paragraph of this paper for the quote cited.
- <sup>20</sup> Comment in the NEJM, posted by the pediatrician Arthur Strauss on July 10, 2013, after the article [Macklin R., Shepherd L., Dreger A., and Asch A.: "The OHRP and SUPPORT -- Another View", New England Journal of Medicine, <a href="http://www.nejm.org/doi/full/10.1056/NEJMc1308015">http://www.nejm.org/doi/full/10.1056/NEJMc1308015</a>].
- <sup>21</sup> Support Study Group of the Eunice Kennedy Shriver National Institute of Child Health and Human Development Neonatal Research Network: "Target Ranges of Oxygen Saturation in Extremely Preterm Infants", posted May 16, 2010, on the website of the New England Journal of Medicine, see page 2 left at http://www.nejm.org/doi/full/10.1056/NEJMoa0911781
- Askie LM, Brocklehurst P, Darlow BA, et al.: "NeOProM: Neonatal Oxygenation Prospective Meta-analysis Collaboration study protocol", BMC Pediatrics, January 17, 2011, see page 7 for the death toll estimate for an unspecified area, as posted at <a href="http://www.biomedcentral.com/content/pdf/1471-2431-11-6.pdf">http://www.biomedcentral.com/content/pdf/1471-2431-11-6.pdf</a>. In fact, the number of 150,000 deaths is probably a serious underestimate even for just the U.S. because an independent extrapolation from a 1960 statistic of a 5% higher mortality from breathing problems in Baltimore produced an estimate of 16,000 extra deaths per year for the U.S. alone, or more than double the officially admitted 150,000 deaths. See <a href="http://retinopathofprematurity.org/26allegedstudyresults.htm">http://retinopathofprematurity.org/26allegedstudyresults.htm</a>, about halfway down that page.
- <sup>23</sup> Bancalari E, Flynn J, Goldberg RN, Bawol R, Cassady J, Schiffman J, Feuer W, Roberts J, Gillings D, and Sim E. Influence of Transcutaneous Oxygen Monitoring on the Incidence of Retinopathy of Prematurity. Pediatrics, May 1987, 79: 5: 663-669,
- <sup>24</sup> Support Study Group of the Eunice Kennedy Shriver National Institute of Child Health and Human Development Neonatal Research Network: "Target Ranges of Oxygen Saturation in Extremely Preterm Infants", as posted May 16, 2010, by the New England Journal of Medicine at <a href="http://www.nejm.org/doi/full/10.1056/NEJMoa0911781">http://www.nejm.org/doi/full/10.1056/NEJMoa0911781</a>
- <sup>25</sup> Askie LM, Brocklehurst P, Darlow BA, et al.: "NeOProM: Neonatal Oxygenation Prospective Metaanalysis Collaboration study protocol", BMC Pediatrics, January 17, 2011, see pages 10 and 11 for the 4 per cent death toll prediction among study subjects, as posted at <a href="http://www.biomedcentral.com/content/pdf/1471-2431-11-6.pdf">http://www.biomedcentral.com/content/pdf/1471-2431-11-6.pdf</a>

<sup>&</sup>lt;sup>26</sup> http://pediatrics.aappublications.org/content/112/6/1415.full.pdf. See page 1418 left

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<sup>29</sup> For a detailed discussion of the lies offered in defense of the SUPPORT experiment, see <a href="http://www.ahrp.org/cms/content/view/925/9/">http://www.ahrp.org/cms/content/view/925/9/</a> by Vera Sharav, President of the *Alliance for Human Research Protection*. This Alliance is a non-governmental organization that tries to fill some of the gaps left by the U.S. Government's timid and overly deferential *Office of Human Research Protections*.

See also my letter to the OHRP in response to the OHRP's invitation to its 8/28/2013 public meeting which I had posted on 6/26 and again on 7/15/2013 at its website and which you can find on the second half of my page

http://retinopathyofprematurity.org/63ProtectHumanResearchSubjects.htm.

<sup>&</sup>lt;sup>27</sup> [Simon N. Whitney, MD, JD. The Python's Embrace: Clinical Research Regulation by Institutional Review Boards, *Pediatrics* 129 (2012). http://pediatrics.aappublications.org/content/129/3/576.full?sid=395f53b6-259b-4654-97b4-

<sup>&</sup>lt;sup>28</sup> See my correspondence with the U.S. *Office of Human Research Protection* at http://retinopathyofpremturity.org/48BioethicsConsent.htm

<sup>&</sup>lt;sup>30</sup> Billy Ryan Looney et al, Plaintiffs, versus Sheila D. Moore et al, Defendants, in Case No.2:13-cv-00733-KOB in the United States District Court for the Northern District of Alabama, Southern Division, Memorandum Opinion of August 13, 2015, by United States District Judge Karon Owen Bowdre.

Dr. Carlo was not the sole designer of this experiment which was part of the international NeOProM group of parallel experiments conceived in 2003 by "an eminent international group of over 30 trialists, bio-statisticians, neonatologists, ophthalmologists, and developmental pediatricians" with the goal to evaluate their results not only individually but also together in a pooled meta-analysis, called NeOProM, for greater statistical discerning power. The other four studies of this group were conducted in Australia, New Zealand, England, and Canada. The Canadian study recruited subjects not only in its own country but also in the US, Argentina, Germany, Israel, and Finland. The NeOProM study is posted at http://www.biomedcentral.com/content/pdf/1471-2431-11-6.pdf

<sup>&</sup>lt;sup>32</sup> At the 8/28/2013 Public Hearing organized by the OHRP, one pair of pained parents came with their then six-year-old cerebral-palsy-afflicted daughter who had also needed eye surgery for retinopathy of prematurity (ROP) and will therefore have life-long vision problems. They asked in anguish whether her conditions had been caused by the research to which she had been subjected behind their backs, despite their doctors' guarantees that her participation in the "risk-free" and merely "information gathering" SUPPORT study would not hurt her in any way.

http://www.youtube.com/watch?v=n1USAH0PMu0. See also a discussion of that Hearing at http://retinopathyofprematurity.org/64KnowinglyHarmfulMedicalResearch.htm

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http://www.al.com/news/birmingham/index.ssf/2015/09/uab study probably did not cau.html by ayurkanin@al.com

<sup>&</sup>lt;sup>33</sup> SUPPORT Study Group of the Eunice Kennedy Shriver NICHD Neonatal Research Network: "Target Ranges of Oxygen Saturation in Extremely Preterm Infants", N Engl J Med 2010; 362:1959-1969May 27, 2010DOI: 10.1056/NEJMoa0911781, posted at <a href="http://www.nejm.org/doi/full/10.1056/NEJMoa0911781#t=abstract">http://www.nejm.org/doi/full/10.1056/NEJMoa0911781#t=abstract</a>

<sup>&</sup>lt;sup>34</sup> As posted at <a href="http://www.nejm.org/doi/pdf/10.1056/NEJMc1007912">http://www.nejm.org/doi/pdf/10.1056/NEJMc1007912</a> by Waldemar A. Carlo, M.D., University of Alabama at Birmingham, Birmingham, AL. <a href="https://www.nejm.org/doi/pdf/10.1056/NEJMc1007912">wcarlo@peds.uab.edu</a>; Neil N. Finer, M.D., University of California at San Diego, San Diego, CA; Marie G. Gantz, Ph.D., RTI International, Research Triangle Park, NC.

http://www.alllaw.com/articles/nolo/personal-injury/burden-of-proof.html.

See also the article: Clear and Convincing Evidence" posted on the Cornell University Law School site at <a href="https://www.law.cornell.edu/wex/clear">https://www.law.cornell.edu/wex/clear</a> and convincing evidence: "A medium level of burden of proof which is a more rigorous standard to meet than the preponderance of the evidence standard, but a less rigorous standard to meet than proving evidence beyond a reasonable doubt. In order to meet the standard and prove something by clear and convincing evidence, a party must prove that it is substantially more likely than not that it is true. This standard is employed in both civil and criminal trials."

<sup>36</sup> https://nei.nih.gov/health/rop/rop

<sup>&</sup>lt;sup>37</sup> Macklin R., Shepherd L., Dreger A., and Asch A.: "The OHRP and SUPPORT -- Another View", New England Journal of Medicine, <a href="http://www.nejm.org/doi/full/10.1056/NEJMc1308015">http://www.nejm.org/doi/full/10.1056/NEJMc1308015</a>

<sup>&</sup>lt;sup>38</sup> For a detailed discussion of the lies offered in defense of the SUPPORT experiment, see <a href="http://www.ahrp.org/cms/content/view/925/9/">http://www.ahrp.org/cms/content/view/925/9/</a> by Vera Sharav, President of the *Alliance for Human Research Protection*. This *Alliance* is a non-governmental organization that tries to fill some of the gap left by the U.S. Government's timid and overly deferential *Office of Human Research Protections*.

<sup>&</sup>lt;sup>40</sup> John D. Lantos, Perspectives in Biology and Medicine, University of Chicago Press, Autumn 1996, pages 78-92, quotes on pages 80, 81, 84, 87, and 91.

- <sup>43</sup> Tin W, Milligan DW, Pennefather P, Hey E. "Pulse oximetry, severe retinopathy, and outcome at one year in babies of less than 28 weeks gestation", (Arch Dis Child Fetal Neonatal Ed 2001;84:F106-F110). See their pdf page 1 right, bottom, and continued on page 2 left, top, for quote.
- <sup>44</sup> As posted at <a href="http://www.nejm.org/doi/pdf/10.1056/NEJMc1007912">http://www.nejm.org/doi/pdf/10.1056/NEJMc1007912</a> by Waldemar A. Carlo, M.D., University of Alabama at Birmingham, Birmingham, AL. <a href="http://www.nejm.org/doi/pdf/10.1056/NEJMc1007912">wcarlo@peds.uab.edu</a>; Neil N. Finer, M.D., University of California at San Diego, San Diego, CA; Marie G. Gantz, Ph.D., RTI International, Research Triangle Park, NC. They cite the experts who had recommended those even lower levels of oxygen saturation as: **4** Laptook AR, Shalhab W, Allen J, Saha S, Walsh M. Pulse oximetry in very low birth weight infants: can oxygen saturation be maintained in the desired range? J Perinatol 2006; 26:337-41.
- <sup>45</sup> Molière: "The Imaginary Invalid", Paris, 1673, Act 3; translation by John Wood, Penguin Books, 1959, page 258.
- <sup>46</sup> Biography of John P. A. Ioannidis at <a href="https://med.stanford.edu/profiles/john-ioannidis">https://med.stanford.edu/profiles/john-ioannidis</a>
- <sup>47</sup> See also the article "Lies, Damned Lies, and Medical Science" by David H. Freedman in the November, 2010, issue of *The Atlantic*, posted at <a href="http://www.theatlantic.com/magazine/archive/2010/11/lies-damned-lies-and-medical-science/308269/">http://www.theatlantic.com/magazine/archive/2010/11/lies-damned-lies-and-medical-science/308269/</a>.
- <sup>48</sup> "Why Most Published Research Findings Are False", posted at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1182327/
- <sup>49</sup> As cited on page 10 of David H. Freedman's above *Atlantic* article.
- See, for instance, Hess JH. "Oxygen Unit for Premature and Very Young Infants". American Journal of Diseases of Children, April 1934, 47: 916-917, see page 917 for birth weights. For more examples dating back as far as 1893, go to <a href="http://retinopathyofprematurity.org/220xygenslander.htm">http://retinopathyofprematurity.org/220xygenslander.htm</a>
- <sup>51</sup> See http://retinopathyofprematurity.org/20oxygeneugenics.htm

<sup>&</sup>lt;sup>41</sup> Reverby SM: "Tuskegee: Could it happen again?", Postgraduate Medical Journal, 7, 2001; 77:553-555.

<sup>42</sup> http://www.nejm.org/doi/full/10.1056/NEJMp1306986rss=searchAndBrowse

- <sup>52</sup> A.E. Samaan: "Harvard and the Holocaust", March 2, 2013, <a href="http://raceofmasters.com">http://raceofmasters.com</a>. For a more detailed and broader account, see Samaan's book: "From a 'Race of Masters' to a 'Master Race': 1948 to 1848", 2012.
- Edwin Black: "War against the Weak: Eugenics and America's Campaign to create a Master Race", Thunder Mouth Press, New York, 2003, page 146. For more information about the eugenicists' promotion of infanticide and their war on blindness, see my account at <a href="http://retinopathyofprematurity.org/20oxygeneugenics.htm">http://retinopathyofprematurity.org/20oxygeneugenics.htm</a>
- <sup>54</sup> "Abstract of Discussion" after Algernon B. Reese, M.D., New York: "Persistence and Hyperplasia of Primary Vitreous; Retrolental Fibroplasia -- Two Entities"; in Archives of Ophthalmology, Vol. 41, Nr. 5, May 1949, paper on pages 527-549, quote on page 550 top, as also cited and discussed at <a href="http://retinopathyofprematurity.org/01Summary.htm">http://retinopathyofprematurity.org/01Summary.htm</a>.
- <sup>55</sup> See, for instance, Martin S. Pernick: "The Black Stork: Eugenics and the Death of 'Defective' Babies in American Medicine and Motion Pictures since 1915", Oxford University Press, New York, 1996, and its discussion at http://retinopathyofprematurity.org/20oxygeneugenics.htm.
- Martin S. Pernick: "The Black Stork: Eugenics and the Death of 'Defective' Babies in American Medicine and Motion Pictures since 1915", Oxford University Press, New York, 1996, see pages 3 to 5, and 86 top, also note 9 on page 192 citing the Baltimore Catholic Review of November 19, 1915.
- <sup>57</sup> Evans PJ. Retrolental Fibroplasia. Transactions of the Ophthalmological Society of the United Kingdom, 1952, 71: 613-16, quotes on pages 613 bottom, 614 top, and 615 middle, as discussed at <a href="http://retinopathyofprematurity.org/220xygenslander.htm">http://retinopathyofprematurity.org/220xygenslander.htm</a>
- <sup>58</sup> For an account of the first oxygen-rationing experiment by Patz and Hoeck, see <a href="http://retinopathyofprematurity.org/22oxygenslander.htm">http://retinopathyofprematurity.org/22oxygenslander.htm</a>
- <sup>59</sup> Kinsey EV. Cooperative Study of Retrolental Fibroplasia and the Use of Oxygen. Archives of Ophthalmology, 1956, 56: 481-543.
- <sup>60</sup> Kinsey EV. Cooperative Study of Retrolental Fibroplasia and the Use of Oxygen. Archives of Ophthalmology, 1956, 56: 481-543, see Table 8A on last, unnumbered, page of Appendix.
- <sup>61</sup> Silverman WA, Blodi FC, Locke JC, Day RL, Reese AB: "Incidence of retrolental fibroplasia in a New York nursery", Archives of Ophthalmology, 1952, 48:698-711, see page 698 for admissions, birth weight, and mortality.

- <sup>67</sup> LOCKE JC, REESE AB. Retrolental fibroplasia the negative role of light, mydriatics, and the ophthalmoscopic examination in its etiology. Arch Ophthalmol 1952: 48: 44 47 (see page 44), as discussed at <a href="http://retinopathyofprematurity.org/37studiesoflightandROP.htm">http://retinopathyofprematurity.org/37studiesoflightandROP.htm</a>
- <sup>68</sup> See my peer-reviewed report "Baby-blinding retinopathy of prematurity and intensive care nursery lighting", latrogenics (The Official Journal of the International Society for the Prevention of latrogenic Complications--ISPIC) Volume 1, Issue 2, dated April-June 1991: 2: 68-85 but distributed in Summer 1992. It is posted on the pages beginning at <a href="http://retinopathyofprematurity.org/Babyblindinglights01.htm">http://retinopathyofprematurity.org/Babyblindinglights01.htm</a>
- <sup>69</sup> GLASS P, AVERY GB, SLUBRAMIANIAN KNS, KEYS MP, SOSTEK AM, FRIENDLY DS. Effects of bright light in the hospital nursery on the incidence of retinopathy of prematurity. New Engl J Med 1985: 313: 401-4, as discussed at <a href="http://retinopathyofprematurity.org/37studiesoflightandROP.htm">http://retinopathyofprematurity.org/37studiesoflightandROP.htm</a>

<sup>&</sup>lt;sup>62</sup> For a good example from a series of books by medical doctors about the inherent flaws in the current medical culture, see Marty Makary, MD: "Unaccountable – What Hospitals Won't Tell You and How Transparency Can Revolutionize Health Care", Bloomsbury Press, New York, 2012.

<sup>&</sup>lt;sup>63</sup> as quoted and documented at <a href="http://retinopathyofprematurity.org/29futilityandharm.htm">http://retinopathyofprematurity.org/29futilityandharm.htm</a>

<sup>&</sup>lt;sup>64</sup> Support Study Group of the Eunice Kennedy Shriver National Institute of Child Health and Human Development Neonatal Research Network: "Target Ranges of Oxygen Saturation in Extremely Preterm Infants", posted May 16, 2010, on the website of the *New England Journal of Medicine*, at <a href="http://www.nejm.org/doi/full/10.1056/NEJMoa0911781">http://www.nejm.org/doi/full/10.1056/NEJMoa0911781</a>

http://www.uab.edu/medicine/peds/neo-patient-info/rnicu-ccn-info/35-neonatology/497-lower-oxygen-eye-damage, published May 16, 2010 by Waldemar A. Carlo, MD

<sup>&</sup>lt;sup>66</sup> http://retinopathyofprematurity.org/Babyblindinglights01.htm

<sup>&</sup>lt;sup>70</sup> Reynolds JD, Hardy RJ, Kennedy KA, Spencer R, van Heuven WAJ, Fielder AR for the LIGHT-ROP Cooperative Group: Lack of Efficacy of Light Reduction in Preventing Retinopathy of Prematurity, NEJM May 28, 1998, 338 (22):1572–6. See the discussion of the frauds in this experiment at <a href="http://retinopathyofprematurity.org/40fraudsinLIGHTROP.htm">http://retinopathyofprematurity.org/40fraudsinLIGHTROP.htm</a>. Also, some of the most incriminating portions from the Manual of Procedures for that rigged LIGHT-ROP trial are posted on the pages beginning at <a href="http://retinopathyofprematurity.org/LIGHT">http://retinopathyofprematurity.org/LIGHT</a> ROP Manual01.htm

<sup>&</sup>lt;sup>71</sup> https://nei.nih.gov/health/rop/rop, at the end of the section "Are there other risk factors for ROP?"

http://money.cnn.com/news/newsfeeds/articles/prnewswire/enUK201412092875.htm.

<sup>&</sup>lt;sup>72</sup> as cited in Weiter JJ. Phototoxic Changes in the Retina, in Miller D. (ed.): Clinical Light Damage to the Eye, Springer Verlag, New York, 1987, pages 79-125, see pages 86 and 122.

https://openpaymentsdata.cms.gov/company/10000005698 and https://openpaymentsdata.cms.gov/physician/512755 for payments to Steven Barker

<sup>&</sup>lt;sup>74</sup> <a href="http://www.prnewswire.com/news-releases/new-multi-center-study-finds-clinical-practice-change-with-masimo-set-pulse-oximetry-reduces-severe-eye-damage-more-than-50-in-premature-newborns-104090258.html">http://www.prnewswire.com/news-releases/new-multi-center-study-finds-clinical-practice-change-with-masimo-set-pulse-oximetry-reduces-severe-eye-damage-more-than-50-in-premature-newborns-104090258.html</a>

<sup>&</sup>lt;sup>75</sup> See, for instance, the "Research and Markets" report of November 11, 2014, at <a href="http://www.businesswire.com/news/home/20141111005741/en/Research-Markets-Global-Retinopathy-Prematurity-Therapeutics-Pipeline#.VJAE6cmrFHM">http://www.businesswire.com/news/home/20141111005741/en/Research-Markets-Global-Retinopathy-Prematurity-Therapeutics-Pipeline#.VJAE6cmrFHM</a> and the CNN Money Report on Shire R&D about their SHP607 protein replacement therapy being developed for the prevention of ROP, as posted at

<sup>&</sup>lt;sup>76</sup> See, for instance, <a href="http://www.soundandvision.com/content/led-vs-cfl-bulbs-color-temp-light-spectrum-and-more#JfRxPKTt2LTqFxbl.97">http://www.soundandvision.com/content/led-vs-cfl-bulbs-color-temp-light-spectrum-and-more#JfRxPKTt2LTqFxbl.97</a> and <a href="http://www.popularmechanics.com/technology/gadgets/reviews/g164/incandescent-vs-compact-fluorescent-vs-led-ultimate-light-bulb-test/">http://www.soundandvision.com/content/led-vs-cfl-bulbs-color-temp-light-spectrum-and-more#JfRxPKTt2LTqFxbl.97</a> and <a href="http://www.popularmechanics.com/technology/gadgets/reviews/g164/incandescent-vs-compact-fluorescent-vs-led-ultimate-light-bulb-test/">http://www.popularmechanics.com/technology/gadgets/reviews/g164/incandescent-vs-led-ultimate-light-bulb-test/</a>

<sup>&</sup>lt;sup>77</sup> See, for instance, <a href="http://retinopathyofpremuturity.org/ROPTVGoodMorningAmerica.htm">http://retinopathyofpremuturity.org/ROPTVGoodMorningAmerica.htm</a> for a transcript of my August, 1989, live TV discussion on Good Morning America with Dr. Gerald B. Merenstein, Chairman of the Committee on Fetus and Newborn of the American Academy of Pediatrics, Professor of Pediatrics and Acting Chairman of the Department of Pediatrics at the University of Colorado in Denver, in which this "expert" claimed, contrary to his own earlier writings and his presumed knowledge that babies come from dark wombs: "Even something as simple as keeping the lights very low may have an adverse effect that we are not aware of".

<sup>&</sup>lt;sup>78</sup> I sent the initial version of my paper about baby-blinding nursery lights to both *Pediatrics* and *JAMA* in October, 1987, and followed up several times since then.

<sup>&</sup>lt;sup>79</sup> For my most recent correspondence with the *NEJM*, see http://retinopathyofprematurity.org/60NEJMcoverup.htm

<sup>&</sup>lt;sup>80</sup> <u>http://retinopathyofprematurity.org/HypocriticalNature.htm</u>

<sup>81</sup> http://retinopathyofprematurity.org/61PLoSMedicineCoverup.htm

<sup>&</sup>lt;sup>82</sup> Bloomsbury Press, New York, 2012