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Fake science and bogus bioethics: medical research frauds against premature babies

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Abstract

The epidemic of baby-blinding retinopathy of prematurity continues because of several blatantly rigged clinical trials. Misled neonatologists withhold life-saving breathing help from premature babies because of one eugenics-inspired fraudulent study from fifty years ago that was never replicated but was used to disguise an euthanasia program designed to eliminate preemies with a wrongly postulated “genetic” blinding defect. Their so contaminated doctrine prevents them from acknowledging the real cause of the blinding which is the lighting that they have specified for the intensive-care nursery. The mandated fluorescent lighting concentrates much of its energy in the most eye-damaging wavelength region and thereby creates a steady stream of preemie customers who need expensive patch-up treatments. The efforts to deny this embarrassing reality have led to further rigged studies that mocked science and abused patients. None of the bioethicists informed about these unethical practices spoke out against them; and the relevant medical U.S. government agencies have helped with the cover-up. The continuing longevity of the baby-blinding research frauds exposes the myth of the often-touted mechanism of self-correction in science and confirms the reality of strong error-preserving factors in the medical culture that undermine the credibility of all clinical research reports.

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Keywords: retinopathy of prematurity, intensive care nursery lighting, medical research frauds

1. Introduction and background

The brilliant accomplishments of modern medicine are being badly tarnished by its antiscientific and dishonest approach to the epidemic of blinding among premature babies, which is called retinopathy of prematurity, or ROP. For over fifty years, and counting, neonatologists around the world have been withholding supplementary oxygen breathing help from premature babies as an alleged prevention against ROP. Their rationing of this life-saving gas has helped kill tens of thousands of preemies and caused severe permanent brain damage to many others, but it has never been shown to mitigate the blinding observed. It does not even have any theoretical justification since no one can control or even measure the independent oxygen levels in the retinal blood vessels where alone they would count. However, this baby-harming doctrine still dominates the modern preemie treatment industry so much that oxygen management accounts for about a third of the billings from a typical intensive care nursery.

The entire elaborate ritual of oxygen management for preemies is based on one clearly fraudulent and never replicated multi-hospital trial that was held in 1953/54. This bogus trial pretended to establish a relationship between the administration of oxygen and ROP. Moreover, it may well qualify as the most deceptively designed and most persistently damage-inflicting clinical study from a period of often notoriously unethical medical research that also brought us the long-unscrutinized *Tuskegee Study* and the equally infamous mid-century *Human Radiation Experiments*.

A group of leading American nursery doctors held this knowingly misleading oxygen trial to introduce withholding of oxygen from premature babies as a means to end the ROP epidemic that was overwhelming their country’s facilities for the care of blind children [1].

As documented in Section 2 of this five-part article, the eugenics-inspired designers of this bogus trial rigged it to simply reduce the number of survivors who might have gone blind. They had previously proposed to weed out the “defective germ plasm” which they wrongly believed to cause the blinding. To eliminate this “defect”, they had advocated “not preserving” the weakest among the enrolled preemies to keep them from growing up blind. Accordingly, they asphyxiated the most desperately gasping newborns in their fake trial by leaving all preemies without any oxygen breathing help for their first two days. Then, they deliberately excluded these deaths from the study results in order to make the oxygen withholding appear harmless.

This trick was rather transparent and should have been caught by any honest reviewer, then or now, because the reported method flatly contradicted the study’s stated aim and conclusion. The study promoters falsely proclaimed that withholding the oxygen had decreased those babies’ risk of blindness without affecting their survival [2]. Their high professional standing and authoritative pronouncements duped the world’s nursery doctors into making the severe rationing of life-saving oxygen the core practice in all intensive care nurseries.

This rationing took a huge toll. In the first decade after that rigged trial, when the oxygen restrictions were tightest, in the U.S. this oxygen rationing practice killed more Americans per year than the Vietnam war. Today, modern neonatologists unwittingly continue to execute a slightly less Draconian version of the systematic asphyxiation policy, which that small group of germ-plasm-suspecting American medical researchers duplicitiously incorporated into pediatric doctrine half a century ago.

None of several later studies succeeded in replicating those phony trial results. However, unlike some of the *Human Radiation Experiments* of that time, the bogus oxygen study has, to this day, not been acknowledged as the fraud it was, and its

rationing of life-saving oxygen still rules the world's intensive care nurseries.

Many modern nursery doctors may follow that lethal part of this deleterious doctrine unknowingly and in good faith, simply because they were trained to trust their teachers and journals. However, some among them are aware of the inconvenient countervailing facts, which are easily verified. But, instead of helping to expose the baby-harming deceit and to correct their standard of practice, they try to keep the fraud hushed up and knowingly continue to harm the babies in their care.

Despite the mantra-like claim of many modern physicians that medicine has become an evidence-based science, this plainly fabricated, and often fatal, fatwa against oxygen usage for premies has remained immune to all the irrefutable and, indeed, never refuted evidence against it. The groundless condemnation of oxygen usage in premies has also helped to prevent naive nursery doctors from seeing the real and rather obviously iatrogenic culprit for the continued baby blinding. That real reason is the eye-damaging fluorescent light the *American Academy of Pediatrics* prescribed for intensive care nurseries. Unfortunately, this embarrassing prescription has led to the rigging of subsequent studies so that their findings failed to find fluorescent light was a factor in the blinding of premies.

Section 3 presents several converging strands of evidence that the damage to the premies' eyes is caused directly by the typical over-bright fluorescent nursery lighting. The light type and intensity specified by the *American Academy of Pediatrics* exposes the babies' still developing retinas during their most vulnerable time to gross overdoses of radiation in precisely the most eye-damaging wavelength region, as defined in the U.S. Occupational Safety Guidelines [3].

However, many nursery doctors have so much faith and investment in their doctrine that they reflexively close their eyes to the damaging role of their nursery lamps in the blinding epidemic.

Maintaining that denial required more lies. Section 4 documents how some pediatric retinal surgeons rigged another bogus study, called LIGHT-ROP, in the mid 1990s. To do this, they grossly overexposed even their allegedly protected "control" group and so falsely exonerated the nursery lamps from any connection with ROP. They thereby prolonged the blinding epidemic, which often requires several costly pediatric retinal surgeries that at best achieve only partial repair.

This further fraud and its uncritical acceptance by the pediatric community highlights a series of dangerous failures in the American medical system. The so-called "peer review" system, on which the credibility of scientific publications is built, has consistently failed to even catch the obvious frauds, glaring factual errors or misrepresentations, and abusive violations of patients' rights in these examples of ROP research. The second supposed line of defense against research frauds consists of various U.S. government agencies, which are supposed to protect patients and public from harmful research practices by enforcing the principles of so-called "medical ethics" and "research integrity". However, all these agencies and so-called "bioethics" commissions condoned the deliberate deceptions in the LIGHT-ROP study and helped, thereby, to continue the cover-up of the real reason for the continued baby-blinding.

This failure of all safeguards against major frauds debunks the often-invoked myth that some postulated self-correcting mechanism in science will miraculously defeat errors and research falsehoods. As the long history of medical obstinacy against reversing doctrinal errors suggests and as the ongoing plight of the premies demonstrates, instead, there is an actual and powerful mechanism in clinical research and medical culture that tends to preserve and enshrine errors.

2. Asphyxiating babies to prevent their blindness

For more than six decades, ROP has accounted for more cases of blindness among children in the U.S. than any other condition. In 2006, the World Health Organization also identified it as a leading cause of vision impairment in children in the developing world [4]. But, despite this importance of the epidemic and reams upon reams of clinical studies about it, modern medical science is now more ignorant of its causes than its discoverer was in 1943 when he suspected right away premature exposure to light as the most logical culprit for this damage to the babies' most light-sensitive organ [5].

Today's neonatologists still follow the baby-harming oxygen rationing doctrine, which a blatant research fraud established half a century ago and which was never confirmed by any of several later studies [6]. They even made that rationing the core of their intensive care nursery routines although their solemn prescribing of a level of oxygen concentration for a premature baby is just as unsupported by any science as the French playwright Molière's doctors' ordering their "Imaginary Invalid" patient to eat only even numbers of salt grains with his breakfast egg.

But whereas Molière's quacks may have been sincere in their caricatured number-magical beliefs, the doctors behind the rigged oxygen-condemning show-trial knew all along that: (a) their prescription was a sham, and (b) the rational use of oxygen has nothing to do with the eye damage.

Apparently, the designers and promoters of the initial fraudulent study lied for what they, and many of their colleagues, thought, at the time, was a worthy, though by then publicly discredited, cause—the medical improvement of the human gene pool. Before anyone ever thought of blaming oxygen for the blinding, some of them had repeatedly stated their firm belief that the blinding was caused by "defective germ plasm." This then-commonly-asserted condition was the proposed cause of many ills from blindness and dementia to chronic poverty and criminal behavior, and the doctors of their generation had learned a ready-made solution to keep such defects from spreading. Many of them had received their medical education in the 1920s and 1930s when the pseudo-science of eugenics was considered cutting-edge medical progress, and they had been taught to value its lofty-sounding goal of improving human evolution by genetic means, such as selective breeding and the elimination of "defective" traits from the gene pool.

The American Eugenics Society was founded in the 1920s, and by 1931, 27 U.S. states had enacted compulsory sterilization laws against the "feeble-minded" and similar ill-defined groups. Several years later Germany, as well as Switzerland, Denmark, Norway, and Sweden passed similar laws inspired by the American model [7]. But, when Americans learned, during

World War II, about the mass murder of handicapped people to which forcible eugenics had led in Germany as a run-up to the Holocaust, the public call for such authoritarian measures fell out of fashion in the U.S.

On the other hand, doctors often tend to stick with the teachings they received during their study years. The sterilizations continued quietly for decades in several U.S. states [8]. The only real change was that the American advocates of new eugenics programs switched after the war to what some of them called “crypto-eugenics” [9] because the newly strengthened public disapproval against their program of “correcting nature’s mistakes” at their source now obliged them to disguise their intentions.

However, some of the nursery doctors involved in that rigged oxygen study had initially discussed their eugenic intentions openly. They had even publicly exhorted their peers to rid the world of that blindness-causing “defective germ plasm” by secretly killing the preemies suspected of carrying it.

Indeed, in May, 1949, a speaker in the discussion after the lead article in one of the *American Medical Association’s* flagship journals, advised its readers in print against preserving the preemies at risk for ROP because they were “defective persons”. He also proposed to ascribe their proposed deaths to “fate”, with his and/or his editor’s quote marks around that word already suggesting the deadly deception these crypto-eugenic opinion leaders had in mind [10].

The most effective means of preserving the weakest preemies was and is to give them supplementary oxygen, which had, by then, a solid and decades-long track record for saving their lives. Accordingly, some nursery doctors launched a smear campaign against that breathing help to brand it as an “undeserved subsidy” that kept the so indulged babies from having to “fight their own struggle for oxygenation.” [11]

Those terms were clearly recycled from the speeches of the eugenics movement, which had opposed all social programs of aid to the poor as damaging distortions of natural selection. They functioned as code words and resonated enough among conservative doctors steeped in eugenic propaganda to make a study of oxygen withholding palatable to them, despite (or rather because of) its predictable risk of death for the weakest preemies.

Although the study designers tried by now to hide their earlier stated scheme of killing the babies at risk for the blinding, their fraud is, and was, obvious from the details of their reported study protocol. To prevent the survival of those unworthy “defectives”, they decided to withhold all breathing help for the first two days from all preemies born in the 18 study hospitals.

During this most critical time of greatest need for immediate breathing help, 45% of those born there died in those first two days [12] compared with, for instance, 32% of the same birth-weight group in their entire first month the year before the trial in one of those study hospitals [13].

Only after so weeding out the weakest preemies with the most vulnerable lungs, who also happen to be those with the most vulnerable eyes, did these doctors enroll the survivors in the study. Not including these pre-enrollment deaths blatantly biased their sample, but they did not acknowledge this heavy

thumb on the risk-weighting scale. Instead, they announced their knowingly false and fatal message that oxygen withholding had reduced the incidence of blinding without affecting the mortality rate.

The physicians behind this deception were respected pillars of the pediatric and ophthalmological professions, and they jointly proclaimed their badly doctored trial result with great authority and pomp as the science-backed consensus of the most qualified top experts. They did not mention that they had loaded the dice in their effort to end the surge of blind children that was by then overwhelming many schools in the U.S. This deception allowed them to slip their crypto-eugenic euthanasia program for the early elimination of potential “defectives” into the neonatologist doctrine under the guise of an allegedly risk-free prevention practice against the then-still-new-but-suddenly-most-common form of childhood blindness.

The resulting mad rush to oxygen withholding almost instantly ended the ROP epidemic because the babies who might have become blind were now dying, plus many others who would have grown up normally.

During the first decade or so after that initial bogus study, misled neonatologists around the world applied its oxygen withholding recommendations very strictly and with many fatal results. In the U.S. alone, an estimated 16,000 extra babies per year died from the oxygen restrictions (see Fig. 1). This mass infanticide ended an ROP epidemic that, until then, had affected there about 2,000 children per year and totally blinded up to about a thousand of them [14].

However, no one counted these early deaths from that first crest of the oxygen-withholding wave until many years later. The annual number of blind children fell back to pre-epidemic levels, and this much-touted victory over ROP helped to convince the U.S. Congress to greatly expand government funding for medical research.

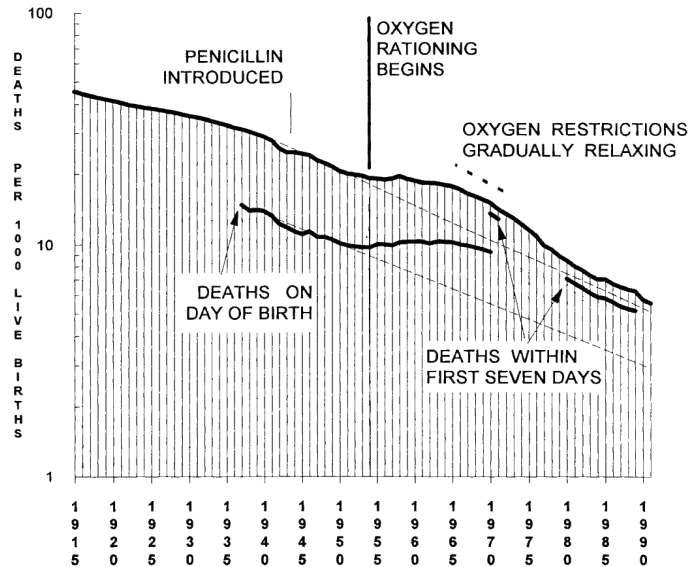
The cost of this victory remained hidden until the early 1970s when two researchers in England and Wales estimated the number of victims. They used different methods than the preceding U.S. estimate, but they obtained a remarkably similar result: in their country, the oxygen withholding had caused about 16 deaths for every case of blindness prevented [15].

There were also reports of a rise in cerebral palsy, spastic diplegia, and other forms of permanent damage to the surviving babies’ oxygen-starved brains. When the magnitude of that carnage and the brain injuries became clear, and the 1960s culture in America led to generally more relaxed attitudes, the nursery doctors there silently relaxed the oxygen rationing rules a little in the mid-to-late 1960s, and some more of the smaller preemies began again to survive.

Despite repeated attempts to replicate the results of that initial oxygen-blaming study, there is no evidence whatsoever for any link between oxygen administration and blinding. However, the *American Academy of Pediatrics* never repudiated the original, but unconfirmable, fraud-based doctrine. Its members know quite well by now that the belief in that link has no scientific or even theoretical basis, but they still restrict the flow of the life-saving oxygen to many preemies, and the result of their supply restriction is still often fatal.

Figure 1. Infant death rates in the U.S. before and after the oxygen withholding study

Sources of data for Figure 1: Neonatal Mortality Rates 1915-1985 from National Center for Health Statistics, Vital Statistics of the United States, 1985, Mortality, part A, sect. 2, page 1, as reproduced in Meckel RA. Save the Babies: American Public Health Reform and the Prevention of Infant Mortality 1850-1929, Johns Hopkins University Press, Baltimore, 1990, Appendix B, pages 238-9; Neonatal Mortality Rates 1980-1989 and Deaths Within Seven Days 1970 and 1980-1989 from U.S. Bureau of the Census, Statistical Abstract of the United States: 1992 (112th edition), Washington, DC, 1992, see No. 110: Fetal and Infant Deaths, page 80 middle; Neonatal Mortality Rates 1989-1991 from Wegman ME. Annual Summary of Vital Statistics - 1991. Pediatrics, December 1992, 90: 6: 835-845. See page 842, Table 7, with data credited to National Center for Health Statistics; Day-of-Birth Death Rates 1937-1969 from Silverman WA: Retrolental fibroplasia: a modern parable. Grune & Stratton, Inc., New York, 1980, rates scaled from Fig. 9.4. on page 65, originally published by Bolton DPG, Cross KW: Further observations on cost of preventing retrolental fibroplasia. Lancet, 1974, 1: 445-448.



Top curve = Neonatal deaths within 28 days of birth, 1915 to 1991; longest curve below it = Death rates on day of birth, 1937 to 1969; two shorter lines to its right = Death within first seven days, 1970 and 1980 to 1989. The top curve prior to 1940 is based on five-year averages. As this graph shows, the infant death rates for the day of birth and for the first 28 days followed an exponential decline before the beginning of the oxygen rationing, like many other undistorted learning curves, but then leveled off and even rose. Each unit on the “Deaths per 1000 live births” scale means between 3000 and 4000 babies who died in the U.S., depending on the total number of births that year.

For instance, like the earlier attempts to replicate the findings of the big *Cooperative Study*, a trial held in Florida and published in 1987 showed again no link between oxygen and incidence or severity of ROP [16]. However, its authors reported 8% more deaths in the group with the then-recommended and tightly monitored oxygen levels than in the group with nominally the same, but less stringently enforced, rationing. Observations such as this one should have led all well-meaning nursery doctors to reexamine the fatal risks of oxygen withholding, because the probability that this mortality increase might be related to the tighter oxygen monitoring was computed as 94%.

Unfortunately, this is not enough of a danger signal for many medically educated minds since their profession’s arbitrary definition of statistical significance considers a correlation as

significant only if that probability reaches 95% or more. Common sense and basic safety considerations would mandate the removal of any avoidable risk that is even weakly associated with death or other harm. However, this widespread medical inability or unwillingness to assess patient safety risks has allowed these harmful oxygen rationing practices to continue.

Meanwhile, in 1988 in one of their meetings, some respected neonatologists admitted that the oxygen-blinding theory is unsupported and meaningless since no one could at that time either measure or control the independent oxygen concentrations in the retinal vessels where alone they would matter in that theory [17,18]. The confusion about the role of oxygen in ROP is so great that some researchers even ran a three-year, 71-hospital study to see whether *increasing* the oxygen levels might help against the blinding [19]. (It did not.) However, so many intensive care nursery routines revolve now around oxygen management that oxygen withholding continues despite the harm it causes to the babies, and despite its total practical as well as theoretical futility.

Moreover, some recently published studies of baby-blinding and oxygen appear now to signal a move back towards re-tightening the oxygen rationing. This trend is again in tune with the current pendulum swing back towards less permissiveness in the American cultural sphere, and also with the resurgence of eugenics, which now cloaks itself with the mantle of genetics. Of course, the harmful oxygen withholding is still unrelated to any scientific evidence, but this bogus doctrine trumps the caregivers’ basic human compassion for the preemies’ often desperate struggle to catch their breath, and it clouds the researchers’ thinking.

For instance, a study published in the February 2003 issue of *Pediatrics* reported on its stricter enforcement of oxygen withholding parameters from 1998 on in one nursery. Unlike most other oxygen withholding studies, this one found a rise in the survival rate of the preemies, but that rise did not coincide with the change in oxygen administration. The survival rate rose very slowly during the first two years of the trial and then only jumped up suddenly while the oxygen policy remained the same. Similarly, the authors also described a striking decrease in severe ROP among the smallest preemies, but again only for the last two years. During the first two years of the oxygen tightening, the blinding and mortality rates remained almost the same as before [20].

This delay before the major increase in the survival rate and the decrease in ROP suggests that both were most likely related not to the oxygen policies but rather to some other change(s) in that nursery. One such change could well have been the switch to better monitoring equipment during the study, though not, as the authors propose, by making compliance with the oxygen restrictions easier. The benefit from the better monitoring equipment may more probably have come from not disturbing the babies as often with ear-piercing alarms.

The stated trial policy was to not turn off the monitor alarms after increasing the oxygen flow until the baby’s blood gas levels returned to the preset range. This inconsiderate policy ensured that the affected babies as well as all their nursery neighbors were often exposed to long bouts of shrieking noise levels even higher than the already dangerously loud pandemonium that is unfortunately common in many intensive care

nurseries. If the new monitors produced less false alarms, as the authors say they did, then the preemies were disturbed less frequently. They got more rest and maybe even some of the fortifying sleep, which a loud environment denies them [21].

Despite the nursery doctors' manifest disdain for such gentle considerations, peace and quiet and rest are essential for all healing and restoration. This noise removal alone could therefore easily have accounted for the babies' better survival, and also for their apparently greater resistance to the retinal damage from ROP.

Despite the better fit of this common-sense alternate explanation with the observed delay in the improvements, and despite the existence of that theory-contradicting delay, the authors described the ROP decrease as consistent after the oxygen policy change. Moreover, in their abstract, which is all most busy readers see, they attributed it entirely to the tightened rationing.

The authors admitted that they could not rule out several confounding factors in their before-and-after comparison. However, such generic warnings are as much of an empty ritual of clinical papers as the mandatory recommendations for further research at their end, and these authors did not examine the most obvious of those potentially confounding factors. Biased reports, like this one, have again fostered an unwarranted impression of progress against ROP with no penalties in the death rate, and they are therefore likely to lead back to tighter oxygen rationing in many nurseries.

Indeed, an Associated Press article by Lauran Neergaard reported on January 28, 2006, that one of that ROP study's authors, Dr. Kenneth Wright from the Cedars-Sinai Medical Center in Los Angeles, "is discussing a multi-hospital study with the National Institutes of Health to prove his findings." Neergaard cited another researcher, Dr. John Penn at Vanderbilt University in Nashville, who "says Wright's work supports his own research that keeping oxygen levels stable seems vital."

Of course, this stated intention and collegial support for the desired outcome preordain the results of this new proposed trial, and so does the profession's need to at-long-last justify its entrenched and nursery-dominating, but still scientifically unsupported, oxygen withholding doctrine. It is therefore likely that most hospitals will again return to "maintaining the babies' oxygen levels at a constant but slightly lower level than usual" as the authors recommend.

Like the initial rigged oxygen-blaming study, this more recent nod towards again reducing the breathing help contradicts a large body of accumulated clinical experience about the brain's continuous need for ample oxygen, and about the bad consequences from depriving it even briefly [22]. This mountain of experience strongly suggests that providing again only minimal amounts of the life-saving gas to preemies in their hours of greatest need is likely to again harm the most vulnerable among them. It will again greatly increase their risks of cerebral palsy, spastic diplegia, and other brain damage as well as death.

But many well-meaning nursery doctors conned by their eugenicist-coined doctrine believe they do the babies a favor when they choke the flow of life-saving oxygen. For all anyone knows, the recent rise in the U.S. infant mortality rate may well

be connected with that returning trend towards tighter throttling.

3. Blinding babies with nursery lights

All this harmful and expensive oxygen management is entirely for naught. Its high costs in lives and disabilities and treatment dollars provide no benefit whatsoever against the blinding because they do not address the real and well-documented cause. Many solidly established scientific facts about light damage to eyes compel the conclusion that the obvious cause of ROP is the excessively bright and eye-damaging fluorescent lighting that the *American Academy of Pediatrics* specifies for intensive-care nurseries.

Neonatologists claim they try to recreate in their nurseries the environment of the womb where the preemies should normally have stayed, but they forget that wombs are dark and protect those babies' still-developing eyes from virtually all light during their most vulnerable period. Even worse, the doctor-specified nursery lamps emit a strong spike of radiation output at 435.8 nanometers, right in the middle of the narrow wavelength region from 430 to 440 nm. This is the very region which the U.S. Occupational Safety Guidelines have identified as the most retina-damaging in the entire visible spectrum, as documented by countless experiments and observations on animals from mice to monkeys and man (see Table 1) [23].

Moreover, the fluorescent ceiling lamps in the typical nursery are the same lamps which neonatologists use in slightly increased strength for the treatment of a preemie's excess bilirubin. In that application as "bilirubin lights", those same fluorescent lamps require mandatory eye patching for the babies beneath them because their radiation would otherwise quickly destroy those babies' retinas even in brief exposures (Fig. 2).

Figure 2. A premature baby with a gauze eyepatch to protect his eyes from the fluorescent light used to reduce high levels of bilirubin in his bloodstream which could cause jaundice and liver damage. The bilirubin therapy lamps deliver only three to five times the irradiation of the standard fluorescent ceiling lamps in typical intensive care nurseries, but the eyes of the babies are not protected from these despite the lack of any safety margin.



For instance, in 1970 a group of newborn piglets, chosen for the developmental and pigmentation similarity of their eyes with those of preemies, suffered marked retinal damage under bilirubin lights. One of them lost its eye patch and became totally blind the next day, after less than 12 hours of exposure, despite its heavy eyelids, thick eyelashes, and the unusually short latency time between the irradiation and the detection of its morbid effects [24].

These bilirubin phototherapy lamps are fluorescent lamps that shine only about three to five times brighter than the fluorescent ceiling lights in a typical nursery. However, most American nursery doctors flatly deny that the almost as strong fluorescent ceiling lights could harm any baby, as if they had never heard of the need for safety margins in the dosage of powerful treatments. For comparison, the U.S. Occupational Safety Guidelines usually set exposure limits to toxic agents at about 1% of the level that causes any discernible damage in test animals.

Yet, the typical nursery ceiling lamps irradiate the unprotected and still developing retinas of the preemies 24 hours a day. There they accumulate in just a few minutes the gross overdose of blue-light damage that the U.S. Occupational Safety Guidelines have set as the danger limit that adult workers should not exceed in an eight-hour shift (Fig. 3) [25].

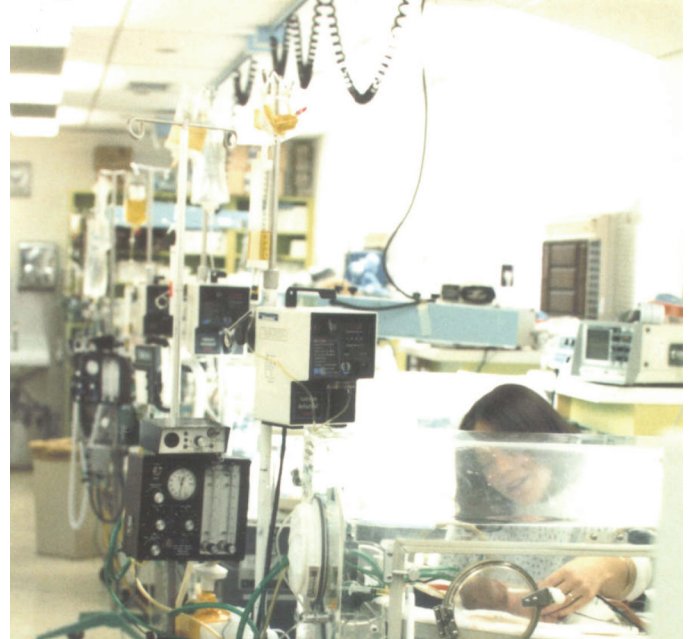
Nursery doctors administer this gross overdose of the most retina-damaging radiation to the preemies during the time of their greatest vulnerability because all living tissues are at their most vulnerable stage during their initial formation when their cells are still migrating and differentiating, just like those in the retinas of preemies. This heightened vulnerability is further increased by the fact that preemie eyes have none of the defenses against excess light that normally protect older people.

To begin with, preemies cannot turn their head away from the ceiling lights or even from the sunshine that is sometimes carelessly allowed to reach their isolettes and even their eyes. In antiquity, it was considered one of the most cruel punishments to make a condemned criminal stare into the sun, but modern nursery doctors sometimes leave innocent preemies casually exposed to that same painful and quickly eye-destroying torture [26].

Preemies also stare a lot with their eyes and pupils wide open, and like older babies, they are particularly attracted by bright areas in their field of view. Even when they close their eyes, their translucent eyelids and still mostly unpigmented iris let through most of the relentless radiation. In addition, their lens has not yet begun the varnish-like yellowing that protects adults from the most dangerous blue and violet wavelengths [27].

To make things even worse, preemies are exposed to many powerful sensitizers, such as medications and even high concentrations of oxygen, which do no harm by themselves but can enhance the free-radical damage caused by strong irradiation. They are also still deficient in many of the minerals and vitamins which could protect them at least partially against those free-radical reactions or which might help their damaged cells to begin their self-repair.

Figure 3. A typical intensive care nursery, with bright banks of fluorescent ceiling lights shining round the clock, and sunlight streaming in during the day through the windows onto the transparent isolettes below them.



The epidemiological evidence against the fluorescent lamps is equally undeniable. There was a precise parallel between their commercial introduction in the U.S. in 1938/39 and the sudden outbreak of the ROP epidemic there less than two years later. That same parallel happened again in the late 1940s and early 1950s across Europe and in many other industrialized countries. As fluorescent lamps became available in those countries after World War II, the preemies in their nurseries suddenly began to get the previously unknown ROP [28]. Retrospective studies among older blind people failed to find any earlier and initially overlooked cases in the U.S. or anywhere else [29].

Electron microscopy tells the same story. It shows that under high magnification, ROP-damaged retinas look exactly like retinas damaged by light, with the same abnormal adhesions between cells that prevent those in the preemie retinas from completing their migration [30].

No one has ever disproved any of that copious evidence against bright fluorescent light. However, American nursery doctors continue their stubborn and irrational denial of eye damage potential from regular nursery lamps even after a trial on human babies found that shading their isolettes had resulted in much less damage to those babies' eyes:

In late 1982, doctors in two Washington D.C. nurseries placed gray filters over the transparent incubators of the preemies and then compared the incidence of ROP before and after this partial light reduction. Their shading produced the most dramatic reduction in both incidence and severity that any of the non-rigged approaches to ROP had ever shown. For the group of babies with the highest risk of ROP, there was only

one chance in a hundred that the eye damage might be a random coincidence and had nothing to do with the light exposure. For all the babies in all the groups together, that chance was given as almost one in twenty [31].

Unfortunately, for some of the heavier subgroups the correlation fell slightly short of the magical 95% probability which doctors are trained to view as the so-called statistical significance level that has to be met when evaluating the efficacy of a treatment.

Moreover, the study authors called the shading a treatment instead of what it really was: a reduction in dosage of the almost bilirubin-strength irradiation treatment which they had been administering indiscriminately all along to all babies under the fluorescent ceiling lights. This semantic confusion prevented the authors and their critics from realizing that the safety of the treatment with light, not the efficacy of its withdrawal, was the real issue.

In safety assessments, one does not wait for harmful effects to reach the arbitrary level of “statistical significance” to recognize them as a problem. Safety professionals take even a weak association with harm as a danger signal, and no caring parents would ever accept the standard fluorescent nursery lamps as safe for their preemie if they knew there are almost 19 chances out of 20 that their light could damage their baby’s eyes.

However, their baby’s doctors deny any danger because from their semantically inverted perspective they fail to see such a risk to their patients as significant.

4. Continued cover-up

Some nursery doctors went even beyond their colleagues’ mere denials that fluorescent light could cause ROP.

In response to public pressure, in 1989, the New York State Department of Health established a Technical Advisory Group on Intensive Care Nursery Lighting that pretended to study the safety of this lighting but ignored and suppressed all the evidence against it. This Advisory Group then issued in 1990 a whitewash report full of fabricated citations and gross distortions to falsely exonerate the current nursery lighting from any role in ROP [32].

Then, on October 22, 1993, a pediatric ophthalmologist at the University of Wisconsin School of Medicine even wrote in the Wisconsin State Journal that “a well-done study conducted in Germany” had found a much higher incidence of ROP among the babies exposed to lower light levels, and that higher light levels may be beneficial to the babies rather than harmful [33]. However, when challenged he was unable to produce any documentation for this patently false statement, but a faculty “ethics” committee at the University of Wisconsin held that this knowingly and dangerously misleading fabrication did not constitute professional misconduct [34].

Despite these attempts at obfuscation, the medical cover-up of the facts about ROP had become so transparent that a more authoritative denial was needed. Accordingly, in the mid 1990s, two pediatric retinal surgeons designed and then co-directed another bogus study, called LIGHT-ROP, which they rigged to falsely support the safety of the nursery lights.

Knowing that the blue-light-damage they pretended to study typically accumulates to harmful levels in just a few minutes,

almost as fast as eye damage from staring at the sun, the LIGHT-ROP authors covered the eyes of the babies in their allegedly protected group only after up to 24 hours of exposure. All these preemies suffered therefore up to 24 hours of unprotected over-exposure to bright fluorescent light shining straight through their still mostly transparent eyelids onto their still developing and therefore extremely vulnerable retinas.

Predictably, and like several earlier shoddy eye-patching studies with the same crucial delay [35], the LIGHT-ROP study found no ROP-difference between its two groups since these had been equally over-exposed to the same multiple overdoses of irradiation during their most critical period. This trick allowed the LIGHT-ROP study authors to again falsely affirm the safety of the standard nursery lighting practices and so to continue the blinding epidemic and the steady stream of ROP patients it supplied for pediatric retinal surgery [36].

Despite the obviousness of this clumsy research fraud, the U.S. medical establishment refused to acknowledge or disavow it, and so did the doctor-staffed government agencies charged with supervising the ethics of clinical trials. None of the alleged ethics watchdogs found anything wrong with the LIGHT-ROP authors’ dishonest study design, nor with their shocking ethics violations when they treated premature human babies like expendable guinea pigs. These authors intentionally increased the exposure of the unprotected control group to the harmful irradiation and even forbade the usual shading blankets over the babies’ isolettes because they wanted “to maximize the contrast between the study groups.” This cruel abuse was approved without question by all the so-called internal review boards that are supposed to examine the ethics of all research proposals submitted to their institutions.

External peer reviewers of that study and editors of respected medical journals did no better. I had repeatedly written to the editors at the *New England Journal of Medicine* to alert them to the gross scientific and ethical flaws in the LIGHT-ROP study. One of them, Dr. Marcia Angell, then Executive Editor, had described earlier a very similar trial design in which a control group had been left unprotected from the suspected dangerous agent, as was then the usual practice, and only the study group received the protection to be tested. She presented this as a textbook example of an unethical trial that should not be published because the researchers had not protected all the subjects in their care from the suspected harm caused by the routine treatment against which they wanted to demonstrate a protection method [37].

This was the same abuse as in the LIGHT-ROP study whose initial designers had stated, “We believe there are compelling reasons to believe that light may play a role in exacerbating ROP.” [38] They had also documented these convincing reasons in compelling detail.

I expected therefore that Dr. Angell would speak out here, too, against the researchers’ failure to protect their subjects from a compellingly suspected danger. Instead, she returned my documentation on August 19, 1996, with a brief letter in which she said only:

“I have skimmed the materials you sent me on lighting and retinopathy of prematurity. Obviously, whether a clinical trial is warranted depends on the prior evidence. The matter would not be studied if there were

absolutely no reason to suspect a connection; on the other hand, clear evidence of a connection between light and retinopathy would render a trial unethical (as well as unnecessary). I do not know the state of the scientific evidence, nor do I have the time and expertise to review the matter. Clearly, you have already brought the matter to the attention of the appropriate authorities.”

Yet, less than two years after being shown the *prima facie* evidence of the scientific fraud and patient abuses in the harm-maximizing and knowingly misleading LIGHT-ROP study, her *Journal* published that very study [39]. It revealed thereby how little its editors follow the ethics policies they claim to enforce. This case also exposes the profession-protecting bias of a review process that ignores well-documented alerts about embarrassing frauds in a paper to be reviewed.

I also brought these ethics abuses as well as the dangers from fluorescent light and from oxygen withholding to the attention of the editors at several other respected medical journals, such as the *Journal of the American Medical Association*, *The Lancet*, and *Pediatrics*, and also several prominent so-called bioethicists. The few who replied at all typically sent form letters that they appreciated my concerns and more research would be needed. None lifted a finger to end the abuses.

Although many of these professionals wear their alleged ethics on their sleeves and assert them often in unctuous speeches, none among them expressed any interest in protecting their country’s preemies from rogue researchers or from routine baby-abusing nursery malpractices. It turns out that “medical ethics” has nothing to do with actual ethics but is simply a synonym for stonewalling inconvenient facts.

Indeed, some medical anthropologists deconstructed several codes of medical ethics from various countries and periods and concluded these were nothing but “... efforts to support professional control by assuring the public that practitioners will use medical resources in morally responsible ways.”[40] The aim of these Potemkin codes is thus not to promote responsible behavior but only its appearance.

This hollowness of scientific ethics codes appeared again clearly when the recent South Korean stem-cell faking scandal made the headlines, as yet another example of fraudulent research. Even though this fraud was outed by exceptionally courageous whistleblowers and not by any of its rubberstamping reviewers, academic defenders of the duped bioresearch journal spun that discovery as proof for the alleged self-correcting mechanisms in their science. These spinners wrote self-righteously that such frauds are rare and pose no real danger because even when they do happen to occur, their new data do not become scientific dogma until they are replicated and thoroughly verified. All is thus for the best in this best of all possible worlds, and “truthiness” reigns.

Yet, the bogus oxygen-blaming study instantly became a doctrine-dominating dogma without any verification, and even without any competent review. This fraud-based dogma has persisted for half a century by now without any correction of its patient-harming flaws. Moreover, it has persisted despite several failed attempts to replicate that bogus study’s fabricated findings, and despite the severe brain damage and death it

caused and continues to cause to many thousands of premature babies around the world.

The faking of the major ROP studies about oxygen and light remains unacknowledged although the frauds in them are so obvious that any attentive reader can easily spot them. You can recognize them yourself because the reported methods and data flatly contradict the conclusions. And you need no medical degree to collect and understand the widely available evidence that oxygen deprivation harms brains, or that bright light harms unprotected eyes.

The automatic wagon-circling reflex of many doctors against any questioning of their doctrine has preserved the fraud-based dogma about ROP for half a century and has even led to further rigging of later research, as in LIGHT-ROP, to help cover up the initial fraud. This still-denied example strongly suggests that the faking scandals which do happen to get exposed represent only the visible part of a much greater hidden iceberg.

Not even the much publicized apologies by President Clinton in 1997 for a long series of past medical ethics lapses in the U.S. changed the fact that, under the current regulations of the U.S. *Office for Protection from Research Risks*, the infamously patient-deceiving Tuskegee Study would again be approved as a matter of course if the same protocol was re-submitted under a different name.

The doctors running that unethical Tuskegee study had failed to protect patients from a known danger just to observe its effects on them. The LIGHT-ROP authors did exactly the same and even prevented nurses and parents from shading the control group babies in their trial. They intentionally maximized the exposure they had described as harmful because they wanted to increase the contrast between the groups [41]. In other words, they exposed the unprotected babies to extra danger just to get clearer study results, cruelly sacrificing those babies to their pretended “science”. Yet, their inhumane protocol fully met the rules of modern American “medical ethics” because the researchers did not introduce a new risk, they only increased an existing one.

Incredible as this may seem to lay observers after the much-publicized official condemnations of the *Tuskegee Study* and of the *Human Radiation Experiments*, the current official U.S. “bioethics” rules still do not require the protection of research subjects from known existing dangers. The researchers still need to protect them only from those dangers that are created by the research itself [42]. Never mind all the official “never again” speeches about those past medical abuses, the phony American “medical ethics” system still officially condones the same type of abuses now.

Meanwhile, the oxygen-blaming and light-ignoring doctrine based on these frauds continues to daily cause much suffering to many children and their families around the world. That suffering may even be getting worse because the medical fashion is now returning to openly blame the old standby of “defective germ plasm” which it has renamed “genetic factors” to suit modern tastes.

ROPARD.org, the official medical fundraising organization for more research about “ROP And Related Diseases”, has attempted for several years to again confuse the issue, just as the original oxygen-study designers had done. To begin with, they falsely imply that ROP is related to other diseases, and they

claim on their website that “ROPARD research has begun to identify a genetic link between premature birth and retinal detachment.”[43]

ROPARD offers no more evidence for this alleged genetic link than there ever was for the “defective germ plasm” theory of the earlier eugenicists that led to the oxygen fraud, or for the healing power in even numbers of salt grains. However, a more recent retrospective study of preemie twins, published in the November, 2006, issue of *Pediatrics*, pretends again to have determined that genes are a major factor in ROP. It states that a component of the analysis “factored in the potential effects of unidentified factors (...) (i.e., [a list of five suspected] variables not available from our data set) (...) in addition to unknown unidentified factors. By modeling the effects of these nongenetic components, we were able to determine that 70.1% of the variance in liability to ROP was attributable to genetic factors alone.”[44]

This precise-appearing assertion is entirely fictitious. Like many of its predecessors in the notoriously fraud-ridden history of eugenic twin studies, it rests on arbitrary ad-hoc estimates fitted to unwarranted assumptions, such as treating the outcomes from twin pairs as correlated events although the study was meant to find out whether these outcomes were related to the genetic similarity of twins. This circular reasoning again highlights the futility of the alleged peer review process for medical papers because the authors’ own words reveal their fallacy. Moreover, their “known” factors, such as the covariates of gestational age and duration of supplemental oxygen use, are statistically inseparable from each other as well as from the incidence or severity of ROP. They can therefore not be mathematically controlled for, as the authors pretend to do, by separating out their postulated influence on the blinding [45].

And the authors’ claim to have controlled their results for several named unknown plus any “unknown unidentified nongenetic factors” owes more to magic, the traditional attempt to wield power over the unknown, than to mathematics, which requires a more rational attitude. By definition, if one wants to control statistically for a factor then this factor and its effects must be known to be so quantified. Anyone who pretends to control for unknown and/or unidentified factors matches *ipso facto* Webster’s definition of a quack: “one who pretends to skill or knowledge which he does not possess.”[46]

This fake study has the scientific value of a horoscope because its authors dress up hunches and predetermined conclusions with elaborate-looking computations the way astrologers do. Yet, this self-evident neo-eugenic nonsense was prominently published in the flagship journal of the American pediatric profession and then gullibly echoed in medical news releases around the world. It has thereby shown again, as during the first and long discredited go-around of selling eugenics as a science, that so-called medical “experts” need no evidence to proclaim whatever suits their agenda.

American medical doctors have long held the status of a *de facto* sovereign profession, and the sad history of ROP confirms that some of them adjust their profession’s doctrine at will to hide its blunders, without concern for truth in their science or for their and their colleagues’ hapless patients. This latest renewal of the old fictitious claims about bad genes involved in ROP is now helping to again divert attention from the profes-

sion’s continued willful ignorance about the fluorescent nursery lighting that actually causes ROP. It also helps to set the stage for renewed crypto-eugenic efforts to weed out the “weaklings” who are said to carry those alleged blinding genes, as an excuse for again giving the babies less breathing help.

If the U.S. Government wanted to be consistent with its much professed concern for preserving the life of unborn fetuses and even of unwanted frozen surplus embryos, then it would stop its nursery doctors from suffocating the weakest among the prematurely born and from damaging the eyes and brains of many others. And if it wanted to reduce its runaway health care expenditures, then it would also keep those doctors from routinely blinding babies with their nursery lamps and from casually inflicting life-long and very expensive cerebral palsy, spastic diplegia, and other brain damage on even more preemies with their ill-advised oxygen rationing.

The unwillingness of American medical officials to admit and correct the pediatric doctrine’s baby-harming and doctor-duping deceptions makes it important for caring neonatologists and future parents all over the world to examine the facts about ROP themselves and to discard those parts of the widely followed American teachings that are based on rigged research and on a dangerously biased agenda.

And commentators who want to reassure the public about the alleged self-correcting mechanisms in science should not limit their sampling to the visible part of the iceberg, that is, the occasional cases of frauds which happened to get exposed despite the strong stonewalling and error-preserving mechanisms in the medical profession. They should also account for the still unacknowledged and often harmful examples where this mythical self-correction plainly failed, as in the medical approach to ROP.

5. Postscript: Early exposure to fluorescent light and early onset of age-related macular degeneration

The medical community’s defensive denials about the baby-blinding properties of fluorescent nursery lighting have kept it from acknowledging that fluorescent lamps are also likely to be significant contributors to yet another epidemic of blinding that now affects the first generation of Americans who grew up under those lamps in their classrooms. The eye disease now known as age-related macular degeneration used to be called senile macular degeneration because people suffered from it only in their old age, typically in their eighties or nineties, and more rarely in their seventies [47]. Over the past two or three decades, however, this degeneration of the central retina began to start earlier and earlier in the lives of the victims, to the point where millions of Americans now lose their central vision to it in their sixties and fifties, and sometimes already in their forties. Meanwhile, age-related macular degeneration has also become the most common cause of irreversible vision loss in the Western world [48].

One of the major factors responsible for macular degeneration appears to be the lifetime accumulation of damage in the retina’s photoreceptors from exposure to harmful light which gradually builds up a layer of debris from destroyed photoreceptors between the remaining ones and so uses up the limited renewal capacity of these [49,50].

As described above, the most harmful light for mammalian eyes is in the blue to violet range, with wavelengths from 430 to 440 nanometers, and fluorescent lamps emit a large portion of their total energy in a narrow spike at 435.8 nm, precisely in the most eye-damaging region. Adult humans are somewhat protected from this damage because our lens yellows with age, just as varnish does, and for the same reason of slow oxidation by free radicals created through long-term irradiation with light. This yellowing filters out much of the blue and violet from about our early twenties on, but these harmful wavelengths can freely penetrate into the still more transparent eyes of children. There they can cause an accelerated buildup of destroyed photoreceptors, which diminishes the capacity of these to self-repair and so ultimately leads to the degeneration of the macula.

It is therefore probably no coincidence that the non-senile people who now experience the much earlier onset of macular degeneration are the first generation who spent much of their youth under fluorescent classroom lamps. The issue has not been studied, so there is presently no proven link between this early unprotected exposure to the most damaging light in the visible spectrum and the earlier appearance of the damage generally connected with this type of exposure. On the other hand, basic logic and elementary prudence suggest to limit this potentially harmful irradiation of your children's retinas until its long-term safety has been established [51].

However, legislators in California and in Australia have recently proposed to replace all incandescent lamps with fluorescent ones for their energy savings. Many other states as well as countries are likely to follow their example with the best of intentions because they are unaware that this technology could bite back, like the once equally touted DDT or chlorofluorocarbons, and cause much more damage down the road than it appears to prevent now. If the early exposure of children to fluorescent light in classrooms is a factor in the later observed accelerated degeneration of their maculae, as the circumstantial evidence suggests, then exposing them also at home to that eye-damaging light is likely to make their vision fail even earlier than that of their parents and grand-parents in the current epidemic of early-onset macular degeneration.

Unfortunately, the medical community is so caught up and vested in denying the obvious danger from fluorescent light to the eyes of preemies that it completely ignores the potential danger from the same lamps to that much larger population. Indeed, none of the experts or agencies charged with assuring the health and safety of our children have issued any public warnings about the potential long-term effects of exposing children to now even more fluorescent light. They are not just asleep at the switch, they do not even want to know that it exists.

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Table 1. Damage weighted irradiance from the "Deluxe Cool White" fluorescent lamp which the American Academy of Pediatrics specifies for intensive care nurseries

Wave-length in nano-meters	Irradiance in watts per 10 nm, scaled from graph	Blue-light hazard function for normal eye	Blue-light damage-weighted irradiance, normal eye	Aphakic eye photic hazard function	Aphakic eye damage-weighted irradiance
315	0.122	--	--	6.00	0.7320
355	0.122	--	--	5.22	0.6368
365	0.955	--	--	4.29	4.0970
375	0.321	--	--	3.56	1.1428
385	0.416	--	--	2.31	0.9610
395	0.581	invisible ultraviolet ↑	--	1.58	0.9180
400	--	0.10	--	1.43	--
405	2.432	0.20	0.4864	1.30	3.1616
410	--	0.40	--	1.25	--
415	0.959	0.80	0.7672	1.20	1.1508
420	--	0.90	--	1.15	--
425	1.137	0.95	1.0802	1.11	1.2621
430	--	0.98	--	1.07	--
435	6.120	1.00	6.1200	1.03	6.3036
440	--	1.00	--	1.00	--
445	1.338	0.97	1.2979	0.97	1.2979
450	--	0.94	--	0.94	--
455	1.440	0.90	1.2960	0.90	1.2960
460	--	0.80	--	0.80	--
465	1.527	0.70	1.0689	0.70	1.0689
470	--	0.62	--	0.62	--
475	1.650	0.55	0.9075	0.55	0.9075
480	--	0.45	--	0.45	--
485	1.727	0.40	0.6908	0.40	0.6908
490	--	0.22	--	0.22	--
495	1.839	0.16	0.2942	0.16	0.2942
500	--	0.10	--	0.10	--
505	1.935	--	0.2419	--	0.2419
515	1.990	--	0.0995	--	0.0995
525	2.118	--	0.0678	--	0.0678
535	2.233	--	0.0447	--	0.0447
545	4.307	--	0.0560	--	0.0560
555	2.476	--	0.0198	--	0.0198
565	2.598	--	0.0130	--	0.0130
575	3.179	--	0.0095	--	0.0095
585	2.905	--	0.0058	--	0.0058
595	2.991	--	0.0030	--	0.0030
600	--	0.01	--	0.01	--
605	3.073	--	0.0031	--	0.0031
615	3.029	--	0.0030	--	0.0030
625	2.952	--	0.0030	--	0.0030
635	2.808	--	0.0028	--	0.0028
645	2.664	--	0.0027	--	0.0027
655	2.355	--	0.0024	--	0.0024
665	2.074	--	0.0021	--	0.0021
675	1.548	--	0.0015	--	0.0015
685	1.021	--	0.0010	--	0.0010
695	0.188	--	0.0002	--	0.0002
700	--	0.001	--	0.001	--
Total	71.130 Watt		14.6 Watt		26.5 Watt
% of output	100%		20.51%		37.26%

Column 1 in this Table lists the wavelengths in nanometers (nm) in which the "Cool White Deluxe" lamp emits its radiation. Column 2 shows the energy of that emission in Watts for each wavelength interval of ten nm. Please note the emission spike at 435 nm. The third column gives the U.S. Occupational Safety Guidelines' action spectrum for the "blue-light hazard function" which the National Institute for Occupational Safety and Health (NIOSH) first published in 1980. It shows the maximum vulnerability range from 435 to 440 nm where the emission from the lamp is strongest. The fourth column multiplies the irradiance from the lamp in column 2 with the value of that "blue-light hazard function" in column 3 to obtain the "damage-weighted irradiance" from that wavelength band that reaches the retina in a normal adult eye. The lens of that eye is usually yellowed and so filters out much of the most damaging blue and violet radiation. Column 5 lists the corresponding photic hazard function for aphakic eyes, that is, eyes like those of preemies whose lens is not yet yellowed and therefore lets through the even more damaging radiation at shorter and therefore more energetic wavelengths. The last column lists the damage-weighted irradiance from those fluorescent nursery lamps on the retinas of unprotected eyes like those of preemies. Its total damage-weighted irradiance amounts to about 20 times the Occupational Safety Guidelines' danger limit for adult retinas.