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How Fauci and Grady Degraded the Standards of Ethical Requirements for Clinical Research in the US Compared to the Rest of the World

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In reading Nuremberg, The Belmont Report, and now the Helsinki Declaration, I can say that up to 2020, US had far lower ethical standards for human subjects research than WMA. Now? None.

Both WHO and the US HHS suffer from a form of ethical blindness when it comes to vaccine research. Foregoing long-term vaccine safety studies in favor of retrospective analysis of real-world data, these agencies fail to recognize that post-marketing (and post-EUA) studies are *de facto* uncontrolled, non-randomized prospective clinical trials conducted without proper consenting procedures.

If you've read the Nuremberg Code, the Belmont Report, and the Declaration of Helsinki, you'd know that protections are supposed to be in place not for *some* people undergoing *some* clinical studies, but instead are considered to be required to be in place for *all* people undergoing *any* clinical studies.

Right now, in our Medical Ethics, Informed Consent, and Human Rights course @ IPAK-EDU, having completed our readings and discussions of The Nuremberg Code and the Belmont Report, we're reading and discussing The Declaration of Helsinki.

Nuremberg focused primarily on the rights of patients' protection from harm by doctors performing "human experiments". Helsinki changed the langued to "clinical research", but the intention was the same. The Belmont Report was an early draft of a guidance-type document in the US meant to inform professionals of the general expectations of normative standards; it is now only considered a "historic" document.

Nuremberg, Helsinki and Belmont carry no legally enforceable language in the US. Instead, Nuremberg and Helsinki were meant to provide international standards by which individual

countries could gauge their governance and regulation of clinical, human subjects research. It takes a while, but comparing the Helsinki Code to the US policies in play prior to 2020 (before COVID) shows that US researchers (meaning US-based pharmaceutical companies) wanted to weaken the concept of *beneficence* – the principle that all involved in a trial should benefit from being part of a clinical trial.

Where the US had departed (prior to 2020) from the rest of the countries that backed Helsinki (WMA) and participated in its updates included, according to Kimmelman et al. (2009) included:

- Disclosure of conflict of interest;
- Public disclosure of study design;
- Benefit for populations in which research is conducted (beneficence);
- Reporting of accurate results and publication of negative findings;
- Access to treatment after research has been conducted, and
- Restriction of use of placebo in a control group where effective alternative treatment is available.

The departure formally came when issues related to HIV clinical trials run in less wealthy countries seemed to depart from Helsinki standards. Rather than work to reconcile differences with Helsinki, US companies, and the US government came up with a different international standard called "Good clinical practice" – standards in place in the EU (codified as Directive 2001/20/EC), and the US (enforced as policy by NIH), all backed by Pharma.

The most well-known sticking point seems to have been the insistence by countries within which US-based pharmaceutical companies were testing their drugs that, at the end of any clinical trial, patients be given access to the best available standard of care for the condition being studied.

But that's just the topic that people feel comfortable talking about.

Each week, my co-instructor, Bernadette Pajer and I discuss and debate the significance and relevance of each of the historic documents – noting of course the temporal relevance. The departure of the US and the EU from the countries that continue to abide by Helsinki serves to empower those running clinical trials at the expense of those individuals taking on the risk of new drugs and vaccines – both in the risk of poor efficacy and in the risk of potential safety issues.

It's time to revisit why and how it came about that the pharmaceutical companies are able to write the rules by which they conduct clinical research.

If you've read my past substack articles, you'll note that I (and others) have called out the FDA for lowering the regulatory bar so low for COVID-19 vaccine "approvals" or "EUA"s that no standard can actually be found.

And of course, you could not help but notice that Fauci was the person pronouncing standards of ethics and dictating his version of reality.

Well, it turns out that Fauci was at the forefront of the war on ethical research, arguing *against* the requirement of the use of placebos in HIV drug trials in Africa:

> "At a recent meeting on AIDS care in Africa, held in Kampala, Uganda, several doctors expressed their concerns about the changes to the declaration. Dr Anthony Fauci of the National Institutes of Health, Maryland, warned the conference of "ethical police" who might not understand the complexities of the situation in Africa." Source

Fauci's insistence on no placebo arm in HIV drug trials in Africa is an example of bluster and posturing on morality to hide the negative consequences (harm) of the drug AZT. We've seen this bluster and posturing all along with COVID-19 vaccines, and Fauci's denial of the efficacy of early treatment. He rolls over so many of the principles of medical research ethics – and ethics of care – those that were meant to be sacrosanct to protect the interests and well-being of individuals, as outlined in Nuremberg, Helsinki, and the Belmont Report.

From Helsinki:

> "Risks, Burdens and Benefits
>
> 16. In medical practice and in medical research, most interventions involve risks and burdens.
>
> Medical research involving human subjects may only be conducted if the importance of the objective outweighs the risks and burdens to the research subjects.
>
> 17. All medical research involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and groups involved in the research in comparison with foreseeable benefits to them and to other individuals or groups affected by the condition under investigation.
>
> Measures to minimise the risks must be implemented. The risks must be continuously monitored, assessed and documented by the researcher.
>
> 18. Physicians may not be involved in a research study involving human subjects unless they are confident that the risks have been adequately assessed and can be satisfactorily managed.
>
> When the risks are found to outweigh the potential benefits or when there is conclusive proof of definitive outcomes, physicians must assess whether to continue, modify or immediately stop the study."

Fast-forward to 2021, from Wikipedia:

> "Early long-term higher-dose therapy with AZT was initially associated with side effects that sometimes limited therapy, including anemia, neutropenia, hepatotoxicity, cardiomyopathy, and myopathy. All of these conditions were generally found to be reversible upon reduction of AZT dosages. They have been attributed to several possible causes, including transient depletion of mitochondrial DNA, sensitivity of the γ-DNA polymerase in some cell mitochondria,[27] the depletion of thymidine triphosphate, oxidative stress, reduction of intracellular L-carnitine or apoptosis of the muscle cells.[28] Anemia due to AZT was successfully treated using erythropoetin to stimulate red blood cell production.[29][30] Drugs that inhibit hepatic glucuronidation, such as indomethacin, nordazepam, acetylsalicylic acid(aspirin) and trimethoprim decreased the elimination rate and increased the therapeutic strength of the medication.[31] Today, side-effects are much less common with the use of lower doses

> of AZT.[32] According to IARC, there is sufficient evidence in experimental animals for the carcinogenicity of zidovudine; it is possibly carcinogenic to humans (Group 2B).[33]"

The mere existence of some treatment does not prove it to be safer – or more effective – than a placebo, yet Fauci acted as though his favorite drug was *fait accompli*. Obviously, his lack of concern over the well-being of people in countries like Africa and India was also racist. No wonder why those in Pharma who want to do research on the cheap & dirty look at Fauci in awe… he's the singular best worst example of an ethical researcher seen in a long, long time.

Medical hubris has been the *modus operandi* of Fauci well before COVID-19.

I found a reference from 1986 in which Christine Grady and Anthony Fauci argued that having an ethical physician in charge of decision-making was more important than informed consent, reversing 70 years of ethical standards first set forth for the Post-WWII era world by the Nuremberg Code. Christine Grady, Chief of the Department of Bioethics, is Fauci's wife. (See this)

Their position is that the world can trust people in white coats conducting human experimentation to be "virtuous" while, at the same time, they write their own rules and set their own standards for "virtue".

We are now, in 2022, in a very bad way as a direct result of Fauci and Grady degrading the standards of ethics for clinical research in the US and for dragging much of the rest of the West with them.

Many people are asking: Who do these people think they are?

It's way past time to stop Fauci & Grady's pattern of using disadvantaged populations, treating those with no voice like lab rats. It's not enough to hold them accountable. It's time we revisit and undo the damage done by Fauci & Grady and map a path for US medical research policies to be brought into alignment with the Helsinki Declaration. It has its own demerits; it's not perfect, but it should serve as a model for reform for biomedical research conducted using US dollars.

Full enrollment for our medical ethics course has closed. But I'm re-opening enrollment today for one week for Video Access Only option so you can watch the past three weeks discussions as Bernadette and I review these historic documents in each class. You'll also receive an email when each new class video is ready. We are discussing Helsinki today at 11:00 AM ET; the video will come out later today.

Next week, we're reading and discussing the Universal Declaration on Human Rights and Bioethics and then we're going to start review US policies in detail.

Click on this image to sign up to receive via email links to our discussions:

Even if this course is not for you, considering joining us in September @ IPAK-EDU for courses that will set your mind ablaze with knowledge, insight & perspective. Explore our courses here.

You can find more about Fauci & those who helped him destroy medical research ethics in the US in Robert F. Kennedy Jr.'s blockbuster book, The Real Anthony Fauci and learn more

about how US policies have involved experimentation in CHD's documentary, "Medical Racism: The New Apartheid."

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Sources

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Nuremberg Code

Helsinki Declaration

The Belmont Report

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