One document, countless lives assured, an industry enabled; 5 documents, the abrogation of diminished human outcomes.

https://downloads.regulations.gov/FDA-2020-D-1138-0112/attachment_15.pdf

https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/information-health-product/drugs/nitrosamine-impurities/recalls.html

https://www.fiercepharma.com/pharma/novartis-sandoz-following-pfizers-lead-triggers-second-carcinogen-recall-week

https://www.bloomberg.com/news/articles/2022-09-01/drug-recalls-for-nitrosamines-could-cost-big-pharma-millions

https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-nitrosamine-varenicline-chantix

https://www.europeanpharmaceuticalreview.com/news/169513/blood-pressure-tablets-recalled-due-to-high-levels-of-nitrosamine/

https://www.merieuxnutrisciences.com/eu/nitrosamines-impurities/

Pfizer Recalls 3 Blood Pressure Medications Over Oncology CNET

https://www.digitalpharmacist.com/blog/recalls-due-to-nitrosamine-legal-action-being-taken/

https://www.cnet.com/health/medical/blood-pressure-medicine-recall-consult-your-doctor-before-taking-action/

J Med Chem. 2021 Mar 25;64(6):2923-2936

https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-nitrosamine-varenicline-chantix

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https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/information-health-product/drugs/nitrosamine-impurities/recalls.html

https://www.medpagetoday.com/cardiology/hypertension/79026

https://www.agilent.com/cs/library/applications/application-method-nitrosamines-sartan-8890-7010b-5994-4618en-agilent.pdf

The Federal Register Administrative Agency rapidly republished this artifact regarding Food and Drug Administration notice of prospective rule making. The list was first mentioned and published in about 2015 or 2016 online and in applications in the USPTO. The document published by the Federal Register Administrative Agency was submitted in the notice period of the federal register because of its merit a scientific document. This vindicates these draft

documents which are difficulty formatted, have voluminous data and have not been thoroughly proofread because of their size, volume and rapid integration of new information, all of which seem to be a challenge in translational research and translational medicine, particularly unfunded translational research and unfunded translational medicine. Resultantly of such publication, recalls of therapeutics, products and services occurred because these clinical indicators are powerful causal and participating factors in diminished clinical and behavioral outcomes. The new documentation set is immensely more powerful than this document, however, the following articles and news present only a minuscule aspect of how this document and the documents which accompanied it, both in submission to the federal register and in publication to regulations.gov website, have empowered clinicians, researchers, pharma. This document and the documents which are to follow, drafts of which are in the github link in the profile on linked in, are likely to change healthcare spending by trillions of dollars in the coming years. Methylene bridge level analysis, are likely to enable abrogation of diminished human outcomes including those resultant of aging, disease and those linked to diminished behavioral outcomes.

It is important to know that the lists of safe therapeutics regarding nitrosamine inclusion are presented as safe because they are in a safe range for what has to be limited studies of how nitrosamines contribute to disease. Nitrosamines inhibit PEMT for s-adenosyl methionine as substrate and nitrosamines result in reduced amines or reduced nitrosamines that must incur additional processing in metabolic, molecular or excretory pathways. Nitrosamines are also formed from, formed on or produce methylene bridge molecules. Thus, nitrosamine increases levels of methylene bridge cysteine and commandeered methylene bridges that can sequester molecular, metabolic, chemical, hydridic, electron or eV- current and translate these into aberrant structure, trap these in isolated nuances of energy pathways, or produce atypical contexts of polymerization within fatty acids, structure otherwise, DNA and RNA. Thus, nitrosamines contribute to disease with other factors in the list of amehsi specification factors, the list of factors in the translational wellness causal indicator API list 1, 2 and 3 or translational wellness causal indicator API list A, B or C. The contribution happens in the manner presented here but most obviously occurs through inhibition of PEMT, causing of expression of anaphylactic response, and increasing the levels of methylene bridge cysteine, all of which are primary factors in most if not all disease.

Nitrosamine contributes to what factors are already in place to cause inhibition of PEMT, increase of methylene bridge cysteine and increase of the intricate anaphylactic response system including upregulation of choline kinase alpha and upregulation of the cdp-choline pathway along with upregulation of proteolysis. Thus, studies that present safe ranges of any of the about 200 or more factors in the three translational wellness causal indicators list are fictional because even trace amounts of nitrosamine in physiology already exhibiting numerous other factors that move methylene bridge cysteine above 3.7 um/L, but typically above 6 or 7 um/L as threshold that increases risk by 99.995 percent, and above 10 um/L to require symptomatic inpatient admission or asymptomatic outpatient/office therapy, including above 15 um/L to require inpatient intensive therapy regardless of if symptoms are exhibited or not. Importantly, dysregulation of methylene cysteine bridge, all intensive purposes or figuratively, is disease, is risk and is the empirical basis of diminished behavior, although trimethylamine-n-oxide may be integral also to such contexts, while inhibition of PEMT by methylene bridge cysteine is cyclic enhancing complexity in disease and deterioration of social behavior. Nitrosamine increases

methylene bridge cysteine and diminishes the function of PEMT, contributing to already exhibited nonresolution cytokines, particulate, xenobiotics, toxins, artificial electromagnetic fields, detrimental social/emotional/behavioral/nutritional/housing statuses, and other factor that may already be in place to diminish PEMT function along with increase methylene bridge cysteine availability. Particular individuals may require much more than the "safe range" to exhibit adverse health or adverse behavior, while others may require only much lower and minuscule levels of nitrosamine to exhibit such adverse outcomes.

Producing perfect therapeutics may be a nearly impossible objective in any civilization's context, although it is one that must be a priority objective in any civilization. Instead of forcing the contrivance of fictional ranges of safe toxicity levels for any factors, civilizations should manage such risk by assuring that its populations are assured a base compensation of 1.25 to 1.50 of the poverty level, assure access to housing, nutrition and quality health services, while paying participants in any essential industry a fair base salary and variable pay that reflects a priority for producing quality and beneficent Human outcomes, such that the result is a civilization that has an incentive to participate as a consumer and as an industry participant role in continuously monitoring, analyzing, improving and assuring outcomes that are optimal. Many clinicians and innovating industries may find themselves unable to counteract the complex status, complications, contexts and outcomes that result when civilizations do not comprehensively assure Human, Social, Behavioral and Physiological requirements incipiently as a foundation for Human and systemic analyses, decisions and social constructs. Producing a fictional context that confuses consumers and even confuses the industry, is probably not the best way to consider the effects of nitrosamine, although the industry obviously is moving to understand and improve these emerging nuances of understanding.

Kudos to the industry, now there is only about 200 or so other such factors that can be applied in assuring Human priority. These should result in massive levels of jobs, massively improved valences, and a more focused galvanization of civilizations toward assured exhibition of Human priority.

It is worth wondering if these artifacts, the program aggregately, and its objectives had been formally funded, if disease and detrimental Human outcomes would even exist any more, although it is also probable that artifacts and outcomes may have been skewed to the status quo in conventional funding contexts? Regardless, the work is obviously disruptive to the status quo. Rock on folks, Rock on.

We have not received any acknowledgement, remuneration or known benefit from information submitted, or the information on the github link which extends this document, although some of knowledgeable industry opinions suggest that the this document and ht information on the github link represented a comprehensive care tensor able to alleviate or prevent disease, detrimental aspects of aging, impairment, injury and diminished behavioral outcomes among Human populations.

The application of the health industry knowledge linked to this profile is able change about 75 percent of all healthcare spending in the world with dramatic increases in optimal Human

outcomes, producing proactive payment that is not destabilizing to economies while producing dramatic proactive prevention of diminished Human outcomes.

The resources are there. Do you already believe that the human experience is to surmount impedance to its assurance? Where do you want to go next and today? Thus, while all among humanity work to change the world into what it requires for the transcendence of Humanity, surely, we will find you out there on the road ahead.