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Opinion Article

Three Decades of Autoimmune Tunnel Vision Directed At Breast Implant Illness, Neurologic Fatiging Syndromes, And Vaccination Induced Disorders

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Introduction

Thirty years ago, in April of 1992, the Food and Drug Administration (FDA) in the USA mandated a moratorium on cosmetic breast enhancement utilizing silicone gel-filled devices. This mandate centered around escalating claims of device-related systemic illness affecting hundreds of thousands of recipients who had these devices placed in their bodies during the 1970's and 1980's. 14 and ½ years later, at the end of 2006, the FDA granted reapproval to Allergan and Mentor to market these devices to the general public. This decision was accompanied by a simultaneous mandate that implant manufacturers conduct prospective studies over the next ten years on 80,000 new recipients to determine silicone breast implant safety. Over the next twelve years, from December of 2006 to December 2018, 2 and ½ million women in the USA became recipients of newly manufactured silicone gel-filled breast implants, the contents of which had been redesigned to contain an "inert cohesive gel." By the end of 2018, 350,000 of these recipients had notified the FDA of grievous systemic ailments that they attributed to their devices (100,000 of whom already had them permanently removed). Corroboration of these complaints by implant manufacturers during their ten-year studies never occurred. However, because of The Freedom of Information Act, we now know what the FDA knew at the halfway mark of these studies, namely that 75% of any ailing participants either (a) had many of their complaints ignored, and/or (b) were lost to follow-up. On March 25th and 26th, 2019 the FDA held public hearings on the topic of silicone gel-filled breast implant illness. Thirty-one months later, in October 2021, the FDA mandated a black box warning and other crucial toxicity information that must be given by surgeons to prospective silicone breast implant recipients prior to any operative procedure.

While all the above was transpiring, alarm bells began going off at The World Health Organization regarding contamination of multiple worldwide environmental compartments by 60,000 other silicone (organosiloxane) commercial products that had been synthesized over the past 80 years for innumerable everyday consumer purchase. Despite "conventional wisdom" propagated by physical chemists that these high molecular weight polymers containing artificial silicon-carbon bonds were chemically and biologically inert, degradation pieces of these molecules began showing up in frogs, seals, honeybees, and routine household inhabitants. During the thirty years that we have witnessed a recurring public health debacle encompassing silicone breast

implant illness, we have also witnessed a marked increase in the prevalence of multiple neurologic fatiguing syndromes in the general population. These syndromes used to be vague and rare, but they are now vague and common. They include (but are not limited to): fibromyalgia, chronic fatigue syndrome/myalgic encephalomyelitis (CFS/ME), dysautonomia, postural orthostatic tachycardia syndrome, small fiber neuropathy, and complex regional pain syndrome. And to make matters even more confusing, over the past three decades both the breast implant and neurologic fatiguing syndrome scenarios have been paralleled by an equal amount of controversy encompassing escalating reports of chronic multisystem vaccine induced disorders, the latter substantially different from the acute vaccine induced autoimmune entities of Guillain-Barre, vasculitis, rheumatoid arthritis, and systemic lupus. Why haven't clinicians and researchers unearthed definitive answers for causation in these three arenas? The answer may actually be quite straightforward. Rheumatologists, neurologists, immunologists, epidemiologists and media personnel appear to be suffering from tunnel vision and are focused almost exclusively on pathogenic concepts of autoimmunity. With regard to silicone gel-filled breast implants, newscaster Connie Chung first aired her startling report in 1990 that women who had been implanted with these devices were complaining of multiple ailments that mimicked features seen in lupus and other systemic connective tissue diseases. At that time the world's published medical literature on the topic of breast implant illness could be summed up in one sentence: silicone gel-filled breast implants, when inserted into a live human being, had the capacity to make the recipient ill. The literature did not specifically state what the illness was (even though it superficially resembled disorders that rheumatologists routinely see), nor did it deduce with certainty that there even was such an illness. Subsequently there transpired a grievous and fundamental error in reasoning: silicone-induced disease was defined in the courtroom before it was properly studied in the exam room. During the drafting of class action litigation in the early 1990's directed against breast implant manufacturers, plaintiff attorneys and defense attorneys (with the assistance of erudite rheumatologists) went to the rheumatology textbooks and extracted the criteria for classical autoimmune systemic connective tissue diseases (e.g., SLE).

They then forged a global class action settlement stating that if anyone with breast implants became ill with one of these disorders they would be compensated. The stage was now set for chaos, which ensued shortly thereafter as a result of three events: (1) instead of 40,000 women showing up at the front door as expected, over 400,000 showed up; (2) there was a timetable to get all of the women examined (by August of 1994); and (3) the legal definition of silicone toxicity became adopted as the medical definition. Examinations of breast implant recipients by board certified rheumatologists were geared towards placing women on a legal compensable grid. Stated another way, the women's ailments were analyzed for what they were supposed to be rather than for what they actually were. This methodology utilized truncated and pre-defined data bases, omitted chronological analysis of disease development, and did not consider alternate mechanisms of disease causation. As an example, the process of manufacturing silicone gel utilizes heavy metals (e.g., platinum) to polymerize silicone oil into a longer and more viscous gel polymer. The heavy metals do not fall out of the soup mixture at the end of this process, and when coupled with the demonstration by the early 1990's that silicone gel bleeds through an intact envelope or shell and disseminates to distant body areas, it is no wonder that 40% of ailing implanted women whom I have examined complain of a metallic taste. Their metallic taste resolved once their implants were removed. Heavy metals are toxic in many ways, especially with regard to one's nervous system (e.g., neuropathies and cognitive impairment), which correlates very well with recipients' complaints of paresthesia and memory lapses. Gel micro dispersion to distant body areas has been verified and occurs prior to device rupture. This is true for any of the multiple generations of devices (including those released for general use since December of 2006).

By the early to mid-1990's it was apparent that silicone gel-filled breast implants elicited an intense local response characterized by the presence of numerous inflammatory and immunocompetent cells in the immediate breast milieu. This led to the assumption that this intense local response would reproduce itself at distant sites, thereby precipitating the systemic ailments manifested by recipients. My bedside observations over the past 32 years were not compatible with that. As an example, synovial fluid analyses from the knees of young ailing recipients in their 30's revealed less than 1,000 white cells and were not representative of joint inflammation common to systemic autoimmune diseases. As another example, in those complaining of dry eyes and dry mouth, salivary gland biopsies were normal. This is analogous to the old Wendy's commercial, "where's the beef?" Yet another clinical observation was equally perplexing, namely muscle biopsies in implant patients with profound weakness were also devoid of any inflammation. These phenomena (and multiple others, such as fatigue, skin rashes, cognitive dysfunction, headaches, hair loss, paresthesia's, abdominal complaints, etc.) occurred in the absence of any pre-existing conditions, and they could not be attributed to any other well-defined disorders. Therefore, multiple other mechanisms of disease causation warranted consideration. This process necessitated: (a) knowledge of the normal and essential integration of the element silicon in higher organisms, and (b) silicon's potential to cause a myriad of biochemical disturbances when its chemistry was altered by the creation of artificial silicon-carbon bonds (the backbone of silicones). Silicon-carbon bonds are a mission impossible for life on earth as we know it, and no living organisms on earth naturally synthesize them. Particularly harmful is the body's inability to deal with the silicone degradation products it produces during the breakdown of large silicone polymers into silanols and silicic acid. Biochemical disturbances can be legion, including (but not limited to): disruption of mitochondrial energy production and energy utilization, chelation of neurotransmitters (e.g., dopamine), mast cell dysfunction, autonomic dysfunction, channelopathies, epigenetic disturbances, alteration of matrix macromolecules, and alteration of the electromagnetic fields of virtually all life-sustaining molecules (enzymes, proteins, DNA, endocrine receptors, etc.).

No other investigator studying silicone gel-filled breast implant illness over the past 32 years approached it in this manner. Many simply assumed that silicone-induced illness would prove to be an autoimmune problem. Sooner or later, along the way, immunologists would bail everyone out by coming up with the proper diagnostic tests. This aberrant and contrived methodology permeated the thought processes of nearly all investigators, yielding the dubious distinction by 1994 of having over 200,000 women examined and very little useful data (with the exception of the escalating reports of device rupture). And once the illness was defined on a fictitious basis, it was a simple matter for implant manufacturers to fund studies showing that the fictitious illness didn't exist. This made short shrift of the legitimate illness, because if a sick breast implant recipient didn't have "A" (something in the textbook), then she didn't have "B" (something new), i.e., she had nothing. The aberrant and contrived methodology was also seized upon by multiple erudite scientific panels, whose conclusions in the latter half of the 1990's led to the erroneous perception that silicone breast implant disease had been permanently laid to rest. The groundwork was now cemented for an inevitable recurrence of this previous public health debacle. The dozens of plausible silicone-induced biochemical disruptions need not necessarily all be operative at the onset of breast implant illness. In addition, these disruptions can also be circuitously interdependent by creating secondary amplification loops that augment and perpetuate each other. Severity of illness may, in part, be a reflection of one's constitutional make-up. These and other factors may contribute to: (a) the heterogeneity of initial symptoms, (b) the diversity of total symptoms and signs that any single individual patient may manifest, and (c) the severity of any single phenomenon a recipient may manifest. For example, disturbances in mitochondrial energy production and energy utilization can be augmented by silicone's ability to produce channelopathies, because ion channels for sodium and potassium are present across mitochondrial membranes. Extensive mitochondrial damage can result in spillage of its organelles which, in turn, are viewed by the body as a bacterial infection.

As another example, the mediators of inflammation released by mast cells readily cross the blood brain barrier and activate brain microglia cells (fixed tissue macrophages) which, in turn, can release their own mediators of inflammation to augment any cognitive changes caused by heavy metals. Even changes in gene expression may occur via the ability of silanols to augment DNA methylation which, in turn, may then account for why one-third of ailing breast implant recipients in some cohort series manifest positive ANA tests. Therefore, although there are many common clinical manifestations of silicone breast implant illness, and although the chronology of disease development follows a dose-response curve, it should not be a surprise that no two patients are exactly alike. The same can be said for any of the diseases that a rheumatologist routinely treats. In rheumatoid arthritis, the onset of the disease is not restricted to one single spontaneous aberrancy in immune regulation. Rheumatoid arthritis has been documented to be initiated by physical trauma, various vaccinations, various infections (including Covid-19), severe emotional upset, insecticide exposure, cigarette smoking, hypoxia, hormonal imbalances, and prolonged exposure to unusual temperature changes. In each of these scenarios the initial activation of inflammatory pathways can be quite diverse, yet these various disturbances all have the capacity to funnel into a common process that results in profound joint destruction.

Patients suffering from chronic fatigue syndrome and other neurologic fatiguing syndromes may manifest a variety of autoantibodies, elevated cytokine levels, and immune dysfunction. But are these abnormalities causative, or are they representative of numerous secondary amplification loops that then circuitously feedback to render chronicity to these illnesses? Stated another way, are these syndromes first initiated via biochemical disruptions due to increasing environmental contamination by 60,000 silicone (organosiloxane) compounds? The recent demonstration of: (a) profound metabolomic anomalies in CFS/ME, and (b) abnormalities of cellular impedance in CFS/ME, would suggest that this may be the case. Mitochondria have hundreds of adaptive mechanisms to neutralize routine environmental contaminants such as insecticides, pesticides, phthalates, and polyhalogenated hydrocarbons (i.e., compounds that do not have artificial silicon-carbon bonds). But when silicones (organ siloxanes) are added to the soup mixture, adaptive mitochondrial mechanisms can easily be inhibited. This is analogous to your house being on fire, but the fire engines cannot get there. In other words, silicones can be "the straw that broke the camel's back." More than twenty different vaccines contain silicones and silica (silicon dioxide). The FDA has never required that these two items be identified as ingredients in any consumer products, including organic foods. Although silica has a long a sordid history of human suffering, and although silicones are clearly not chemically nor biologically inert, the vast majority of vaccine recipients do not develop any chronic immunization sequelae. Recipients who do experience bizarre, protracted ailments after one or more immunizations may be analogous to the post-Covid-19 long haulers who, interestingly, demonstrate numerous post-infectious autoantibodies which may or may not be pathogenic. Stated another way, vaccine exposures to organosiloxane may at times create a perfect storm scenario, whereby initial toxic biochemical disruptions are augmented and perpetuated by secondary "autoimmune" phenomena (caused, in part, by silicones altering the ion channels of regulatory T cells). It should be noted, however, that the extraordinarily huge polymer load in breast implants is, by itself, enough to produce profound morbidity without invoking a perfect storm hypothesis.

For many years clinicians and researchers have grappled with the controversy surrounding the prioritization of evidence-based medicine. The "gold standard" of double-blind, placebo controlled, randomized clinical trials has so monopolized our thinking that it has now not only set off alarm bells in medicine's ivory towers but also in the lay press as well. In the November 2008 weekly Tuesday "Science Times" section, The New York Times correctly exposed the selection bias inherent in such research. Almost all randomized studies are so rigid in their acceptance criteria that they deliberately exclude real world multi-complicated patients seen by legions of clinicians practicing every day on the front lines. Should we really

be less reliant on observational studies, outcome measures, cohort composites and individual case reports, particularly when analyzing breast implant illness, neurologic fatiguing syndromes, and vaccine toxicity? The prior tunnel vision of autoimmune proponents (and not the research venues themselves) may be largely responsible for historically discounting the reality of these entities. Such tunnel vision may also bias the very essence of the teaching process inherent in the day-to-day education of students and residents. Little weight is given to the contention "I have walked through the medical vineyards and have tasted the wine."

Academicians are also fond of ranking medical journals according to their "known expertise." In other words, "obscure" and/or open access journals should not be given the same weight as "prestigious" publications. Enlightenment on the selective methodology of editor's-in-chiefs was the subject matter in the latter half of the 1990's in Brill's Content, a now defunct magazine that critically analyzed such a process in Dr. Marcia Angell (then acting editor-in-chief of the prestigious New England Journal of Medicine). In short, with regard to silicone breast implants, Brill's Content argued that Dr. Angell had her own agenda, first drawing nihilistic conclusions and then setting out to prove them by allowing shoddy articles to be published in her journal utilizing scientific methodology that she generally abhorred. Although possessing an M.D. degree, Dr. Angell never formally practiced medicine, never took care of patients, and never even examined a single breast implant recipient. In her book "Science on Trial" published in 1996, Dr. Angell ridiculed the existence of breast implant illness by utilizing references to suit her purpose, all the while ignoring an entire body of other peer reviewed material authored by proponents of breast implant illness. In her book she also gave Gulf War syndrome the back of her hand as well, but we now know from extensive publications in JAMA in 1998 that Gulf War Syndrome is an epidemiological reality. So much for "prestige."

Any medical practitioner knows that our understanding of disease processes are continuously altered by the evolution of research discoveries. Typical examples include coronary artery disease, bladder cancer, breast cancer, the Covid-19 pandemic, and silicone breast implant illness. In many cases, decades elapse before a medical consensus on changing attitudes is reached. Chronic unchecked systemic inflammation in rheumatoid arthritis is now known to participate in the development of coronary artery disease. Arsenic and fire-fighting chemicals in public water supplies are now known to be risk factors for bladder cancer. Bad dietary habits can adversely alter trillions of bacteria in one's microbiome, thereby increasing one's risk for breast cancer. Adults over age 65, who have experienced multiple naturally occurring viral infections in childhood (e.g., regular measles, mumps, chickenpox, German measles), are now known to have permanent enhancement of the innate arm of their immune system via antigen non-specific immune memory, thereby affording natural resistance to serious illness caused by SARS-CoV-2 (even in the absence of any immunizations against this virus). Since 2018, numerous plastic surgeons in the USA who once viewed silicone breast implant illness with disdain over the previous three decades, have now acknowledged the legitimate existence of this novel entity. These surgeons are now participating in the removal of over 20,000 breast implant devices each year in ailing recipients. Their surgical turnaround has been bolstered by explanation studies demonstrating statistical improvement in recipients' ailments compared to a control group that decided to retain their devices. The silicone breast implant controversy no longer resembles a phonograph needle stuck in a groove on a scratched 33 & 1/3 long playing record for 32 years. The public health debacle crisis of the early 1990's encompassing silicone breast implant illness has clearly been repeating itself ever since these devices were placed back on the market for general use 16 years ago. How long will it take to dispense with the erroneous autoimmune tunnel vision of proponents and nay-sayers who for three decades have monopolized the conversation of this genuinely novel illness? The same question can be asked regarding neurologic fatiguing syndromes and bizarre vaccination induced disorders.

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Conflict of Interest

None.