



Silicone Implants & Connective-Tissue Damage

An Analysis of Risk

The following is an analysis of how humans assess risk, when presented with data and argumentation, and looking at how that assessment of risk is affected adversely when considering the natural psychological biases and effects that have been identified.

At each stage, we will look at which bias or effect is in application, and what the result was. We will further look at the implications and outcomes of such affected risk assessment for the individual and for the society in which they live.

The focus of this analysis is the health scare among US women who believed that silicone breast implants were the cause of severe soft tissue damage, although reference will be made to other medical issues, such as the MMR vaccine linked in some media to the development of autism, to show that the problems associated with faulty risk assessment are not unique, are replicated across various societies and have potentially damaging consequences for all.

This is not a medical or scientific study of what risk if any is posed by silicone breast implants, MMR vaccines, or any other medical procedure mentioned, nor does it make any claims to recommending any particular choice of treatment. It serves only to assess how people assess the risk (often to themselves or their loved ones) of various situations, and why they often mistake how likely is a positive or negative outcome. All data (dates, record of events, media stories) are collected by Dan Gardner, and presented in his excellent work, *Risk*. What follows is a brief and simplified model of Mr Gardner's considerations, with clear examples of how each effect can take hold.

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Time line of events

- 1950s
Japanese prostitutes first develop use of silicone to increase breast size. Silicone is injected directly into breast tissue. This is reportedly done as the increased breast size is considered more attractive to American GIs.
- Early 1960s
Silicone breast implants first manufactured and available commercially.
- 1976
US Food and Drug Administration (FDA) given authority over medical devices. Allowed to demand evidence from manufacturers that device is safe before granting permission for sale.

FDA grants approval for continued sale of breast implants without further evidence, as they had been sold and used for so many years without complaint.
- Late 1970s – early 1980s
Japanese medical journals carry first reports of women who had received silicone injections years previously now diagnosed with connective-tissue diseases such as rheumatoid arthritis, fibromyalgia, and lupus.
- 1982
Australian report describes three women with silicone breast implants and connective-tissue diseases. Although the report made no conclusions, it raised the question of whether silicone could seep into the body, even if no leak or rupture in the implant could be detected.

In the same year, a San Francisco woman sues implant manufacturers, claiming millions of USD for their role in causing her illness.
- 1982 – 1990
Following widespread reporting of both the Australian and Californian cases, concerns rise among women with implants, and doctors. More cases appear in medical literature, and the number of diseases associated with implants grows. So does the number of different media stories.

- 1990
CBS airs episode of *Face to Face With Connie Chung* featuring women who blamed their silicone implants for pain, illness and loss suffered. The television show endorses these views, and the women are allowed to present their individual stories uncritically.
- 1990 – 1992
Stories linking implants with various diseases begin to saturate the media. Headlines such as ‘Ticking Time Bombs’ and ‘Toxic Breasts’ claim that all women with silicone implants face the risk of disease at some time. A Congressional hearing is held as campaigners make the banning of implants a priority.
- Early 1992
FDA gives implant manufacturers 90 days to provide evidence not required earlier that implants are safe for sale. When produced, the evidence is rejected as inadequate.

Dow Corning are instructed to pay 7.34 million USD by a jury in San Francisco, to a woman who claimed implants manufactured by the company had given her ‘mixed connective-tissue disease’.
- April 1992
FDA bans silicone breast implants. In a statement, the FDA emphasises that the implants are being banned only because they were yet proved to be safe, and not because they have been proved to be unsafe.

The chief of the FDA insists that the one million American women with silicone implants have no cause to worry.
- 1992 – 1994
Despite the reassurances, many were convinced that implants were the cause of their various complaints. The few lawsuits became several.
- 1994
Silicone implant manufacturers agree to the largest class-action settlement in history. A 4.25 billion USD fund is created which included 1 billion USD for lawyers.

As part of the settlement, all that was required of claimants was that they prove both that they had received implants, and

that they had one or more of the complaints commonly believed to be associated with implants. There was no requirement to prove that the complaint from which they suffered was caused by the implants, either specifically or generally.

Approximately 500 000 women registered for the settlement (half of all American women with implants), and 250 000 (half of those who registered, or 25% of all women in America with implants) claimed to be suffering currently from one or more implant-related disease.

- June 1994
A Mayo Clinic epidemiological survey is the first proper scientific study conducted into whether there is any provable link between silicone implants and connective-tissue disease. The study, published in the *New England Journal of Medicine* found that no such link existed. More studies follow, all with similar results.
- 1995
Media reports continue. ABC's *Nightline* carries a report into the issue, citing the 'thousands upon thousands of women who have breast implants and complain of terrible pain.

Dow Corning could not meet the demands, and filed for bankruptcy; and the fund collapsed.
- 1995 – 1999
Congress asks the Institute of Medicine (IOM), which forms the medical branch of the National Academies of Science to survey the increasing levels of research.
- 1999
The IOM issues its report. The report concludes that, while "some women with breast implants are indeed very ill and the IOM committee is very sympathetic to their distress... it can find no evidence that these women are ill because of their implants."
- 2004
Dow Corning emerges from nine years of bankruptcy. Part of the reorganisation plan states that the company must create a fund

of more than 2 billion USD to settle more than 360 000 claims.

- November 2006

The FDA lifts the ban on silicone breast implants. The FDA notes that that the devices can rupture or leak and cause pain and inflammation. But it also notes that the very substantial evidence to date does not indicate that they pose a risk of disease.

Anti-implant campaigners are furious, and remain convinced of the deadly properties of silicon breast implants.

Statistical Information

At the time the ban was implemented, there were approximately 100 million women living in the United States of America.

Approximately 1% (100 000) of women suffered from some form of connective-tissue disease.

Approximately 1% (100 000) of women had silicone breast implants.

Reasonable statistical expectations put at 0.1% (10 000) the number of women who might have silicone breast implants **and** suffer some form of connective-tissue disease **by coincidence alone**.

Analysis of factors affecting perception of risk

- Corroborative bias
- Authorial bias
- Narrative bias
- Experiential bias
- Humanisation effect
- Herding effect
- Group polarisation
- Negative bias

Where and when they occur

- Medical reports
- Media reports
- Television 'specials' with women suffering disease
- Courts
- Government bodies
- Lobby groups

- **Corroborative bias**

- “I got sick after these implants... she got sick after these implants... Maybe we are sick for the same reason!”
 - When first feeling sick, no obvious connection is made with implants. The two are merely coincidental.
 - Then a story appears about another woman, with a similar complaint.
 - Further similarity occurs when it is discovered that the second patient also had silicone implants or injections.
 - The timelines are also coincidental – both patients had implants at a similar stage, and both started feeling unwell at a similar stage.
 - Each woman confirms the other’s idea.
 - Two or more women present to the same doctor, who also notes the overlap and similarities between the cases.
 - A first medical report is produced, questioning the potential link.
 - Others with similar conditions and complaints see the possible link as **the** reason for their suffering.
 - The first case reaches court, garnering further publicity, and providing a forum for an examination of the facts – but not a scientific study.
 - The first settlement of a case brought to court appears to confirm what many victims think they know – implants cause connective-tissue damage.
 - The knowledge of one’s own case is reinforced by the jury’s affirmation, the decision of the court (leading to authorial bias), and the acceptance of the judgment (leading to experiential bias).
- “Now there are more stories of women with implants (or injections) getting sick...”
 - Anecdotal reports increase in number, all showing coincidental silicone implant treatment and subsequent disease.
 - Media begin to carry the story, in print and on television.
 - The personal nature of each story is examined (leading to narrative bias).
 - As more individual stories appear, the similarities among the various cases are highlighted, and become the focus of the story.
 - The successful court case brings about class actions against the manufacturers, and the formation of campaign groups.

- Both of these require more women to come forward, so advertisements are placed, asking women who have connective-tissue disease and implants to come forward.
 - No appeal is made for women with implants and no disease to come forward, nor for women who suffer from the disease but have had no silicone implants.
- “My doctor thinks there may be a link...”
 - Doctors are confronted with more and more individual cases.
 - The patients are themselves convinced of the cause of their disease(s).
 - The doctor searches non-media stories and non-anecdotal reports to see if any link may be possible.
 - The discovery of similar cases apparently discovered by doctors in other countries reinforces the idea of a potential link (leading to authorial bias).
 - The doctors’ apparent agreement that a link might exist is taken as confirmation by the patient that the link has been *proven* to exist.
 - The growing acceptance of a possible link in medical circles appears to confirm media speculation into the risk
 - Medical ‘evidence’ given in support of cases affirms individuals’ and media speculation, and is in turn affirmed by verdicts.
- “They are paying out to settle cases...”
 - Medical evidence, jury verdicts and judgment of the courts all confirm the apparent link between silicone breast implants and connective-tissue disease.
 - Settlement of further cases out of court is seen as contrite behaviour on behalf of the manufacturers.
 - The possibility that out of court settlements are made based on financial concerns only is not considered.
 - Following the manufacturer’s behaviour accepting financial settlement as a remedy, the outcome of further cases is seen as a given.
 - A multi-billion dollar fund is created to pay off all claimants who can prove coexistence of implants and disease, without needing to prove causality.
 - Further calls are made for more women to come forward and claim from the fund.

- **Authorial bias**

- Doctors' anecdotal beliefs
 - The first woman who suspects a link may have that suspicion allayed by her doctor. So may the second and third and fourth...
 - One doctor sees repeat cases, and starts to wonder themselves whether there could be some connection
 - They notice strong similarities between the cases (time lapse between insertion of implants and development of disease, &c.) and decide to write a study of the patients for a medical journal.
 - The journal article is read and discussed by other doctors.
 - They begin to notice a rise in the number of patients claiming their implants have made them ill.
 - Their own experiential bias leads them to affirm and even encourage the patients' beliefs.
 - In discussion with other doctors, these beliefs strengthen and intensify (herding effect).
- Medical reports of possible links
 - The study focuses on the similarities (corroborative, or pattern bias) and questions the existence of a possible link
 - The conclusion of the study is rightly that a full scientific study should be completed.
 - The report is read by a doctor, who has patients with similar complaints.
 - They contact the authors to discuss the cases, and the possible links.
 - As the discussion focuses on similarities, each doctor becomes more convinced that what links these women most strongly (given the potential variance in age, geography, lifestyle, &c.) is the coexistence of implants and connective-tissue disease.
 - Each affirms and reaffirms the other's belief that a link might exist, and that any future scientific study might also confirm the link (corroborative bias)
 - A body of medical opinion (as yet unsupported by medical evidence) begins to build
- 'Serious' investigative journalism
 - Prime-time television shows carry extensive and in-depth reports to the issue
 - All the focus is on the human side of the story (humanisation effect)

- Victims are allowed to present their case unchallenged
 - Anecdotal rather than scientific data is presented as fact
 - The programme makers and journalists seek out only those women who have implants and the disease.
 - Nobody is interested in women with implants who are free from disease, or women with the disease who have no implants.
 - Mainstream media coverage of medical journal reports focuses on individual stories (humanisation effect, narrative bias) and the obvious similarities (corroborative, or pattern bias).
 - Each story strives to be more extreme, to find the ultimate victim, the greatest suffering (herding effect).
- Courts' decisions
 - The court is seen as a place to test evidence, but no distinction is made between legal and scientific evidential burdens.
 - The court is asked only to adjudge the probability of a link between implants and connective-tissue disease.
 - In hearing medical opinion in court, the number of claimed cases gives weight to the possibility of a link.
 - The acceptance of the verdict and judgment reinforces the 'correct' nature of both.
 - Successful cases lead directly to appeals from class-action lawyers and pressure groups for more women to come forward (corroborative bias).
- FDA statements
 - The call for evidence of safety in 1992 is seen as a direct response to the growing body of cases claiming that implants cause connective-tissue disease.
 - The manufacturers are asked to prove 'safety', not the absence of a link.
 - Evidence is provided, within 90 days, but is rejected by the FDA as 'inadequate', and the ban is imposed.
 - Attempts to assure American women that a lack of proof of safety does not equate to proof of a lack of safety fail as the 'safety first' message of an outright ban confirms the fears of women with implants (corroborative bias).
 - Later statements and the lifting of the ban appear to do little to alter perceptions of campaigners (herding effect).

- **Narrative bias**
 - Media reports focused on individual women
 - Media do not carry initial medical reports of women with connective-tissue disease.
 - As numbers of individual stories grow, the trend or pattern appears to emerge (corroborative bias).
 - The lack of hard scientific evidence is seen as more reason, not less, to suspect a possible link.
 - The potential of a scandal, or cover-up, creates intrigue in the story.
 - The medical reports provide a basis for a story, but the conclusion that a scientific study is needed to determine any link is unsatisfactory.
 - A more interesting story is from the victims themselves (humanisation effect).
 - The harrowing nature of the story makes it hard to deny face-to-face.
 - The victims' certainty reaffirms the suspicion of the reader and viewer (corroborative bias).
 - CBS and ABC specials, with victims' testimonies
 - The nature of the programmes is that one story is investigated in depth.
 - Evidence is amassed in anecdotal form, and presented uncritically.
 - The assumptions of the victims form the starting point of presenters' questions – 'how could this happen?'; 'why is nothing being done?'
 - The wide dissemination of the network programme breaks the story nation-wide.
 - Legal cases create a ready-made framework for the narrative
 - The classic tale of the small but determined individual who takes on big companies and wins
 - When the verdict is returned, it conforms to what is believed should happen (corroborative bias).
 - People wait eagerly for the next underdog to triumph.

- **Experiential bias**
 - Increasing number of media reports
 - Initial reports appear to be isolated cases, simply noting that there may be a link
 - As more women come forward asserting that they too are suffering, the reports increase
 - Reports making direct links between the cases increase exposure to individual stories
 - Increasing number of women making similar claims
 - Support groups and campaign groups are established as women seek others who understand their condition
 - The presence of such groups receives its own coverage in the media
 - The corresponding rise in the number of stories and circulation of those stories encourages more women to come forward to seek support and help
 - Increasing number of diseases linked to implants
 - As reports of individual cases grow, women suffering similar but not the same disease begin to link their condition to implants, based on time lapse between procedure and illness
 - Specialists note the similarity between different diseases, and how some like conditions could in theory be caused by the same event
 - Increasing number of successful court cases
 - Women watch the early court case for an indication of how successful their own legal action might be; as early cases are settled in favour of the plaintiffs, more women have confidence in seeking legal redress
 - As the number of cases pending proliferates, the manufacturers have a to make a financial decision as to whether they should keep fighting, or settle out of court
 - The economic decision in favour of settling affirms the idea that they are responsible, causing a fresh wave of cases.
 - The establishment of a fund to settle all cases where coexistence can be shown, with no need for causality to be proved, cements that idea illness occurs after implants are introduced, and there follows compensation.

- **Humanisation effect**
 - Individual stories' focus on single cases
 - 1 million women could be affected if the link exists
 - Medical reports must deal with the case, not the personal story, because of confidentiality. Thus reports of 'Patient M' and 'Patient W' appear, but do not cause widespread panic
 - First media reporting needs to make the story more interesting for consumers (narrative bias)
 - The focus of such stories is then on the family life of the woman, the loss of amenity and pain she has suffered, and the effect of her illness on her children, husband and family.
 - **Note:** the IMO report commissioned by the FDA and delivered in 1999 acknowledges the pain and genuine suffering of many women with both silicone breast implants and connective-tissue disease whilst at the same time denying that the implants have any causal role in the disease.
 - Media stories continue to focus on the undeniable pain, loss and suffering of the subjects of the stories whilst downplaying the 'link'
 - Women appearing to give tearful reports of pain, suffering and loss on prime time television
 - "I had implants and then I got sick..."
 - The statement is entirely accurate. There is no disputing the fact that the illness occurred after the implants were received.
 - "Look at me now..."
 - The physical evidence of illness is equally undeniable; the women look, and genuinely are, sick, and are in pain.
 - "I'm sorry, I'm just so angry... It's not fair!"
 - Again, this is true; what has happened to these women is unfair, and pitiful. Their emotional response (weeping, anger, wanting to apportion blame) is entirely reasonable.
 - There is no contradiction of each woman's view that the implants cause the illness, for fear of being seen to accuse a clearly ill woman of lying

- Extensive media coverage of individual successes in court
 - Court cases are by nature arenas for personal tales of triumph and disaster
 - The familiar story is set – poor individual set against rich corporation, small against big, weak against strong, (for some campaigners) woman against man (narrative bias).
 - As one woman is successful, media reports portray her as a woman fighting not for money but for truth, justice and women in pain and suffering everywhere.
 - The size of the payout magnifies these feelings of heroic deeds, as all agree the place to hurt these shameless companies who profit so much from the suffering of others is in their pockets.
 - The success and large payout of one feeds the success and large payout of the next (experiential bias).
 - Lawyers recognise the potential income stream from multiple or class actions.
 - Advertising begins in earnest for new claimants to come forward (experiential bias).
 - New claimants are advised on the likely success of their claim based on similarities (corroborative and experiential bias)
 - The sheer number of claims causes the manufacturers to consider out of court settlements as a more economical option.
 - The apparent admission of complicity and liability the out of court settlement creates is widely reported in media as a victory for the crusading lawyers who took on the case, increasing individual profiles.
 - These lawyers receive generous personal coverage in media, affirming their position as on the side of good, and battling the evil forces of the manufacturers, succeeding against the odds (narrative bias).

- **Herding effect**
 - Support groups created for victims
 - As each new member is welcomed into the group, her individual suspicions are confirmed by all other members (corroborative and experiential bias).
 - As those views are affirmed by the group, she may grow more confident in asserting them outside the group.
 - This may lead to further dissemination of the view, and further reinforcement as others voice agreement.
 - Other new contacts with experience (and thus experiential bias) are invited to join the group.
 - Because the group is reliant on numbers, any woman who may have any condition that may be linked to implants is welcomed.
 - The lack of the same condition, time lapse, &c. is seen not as a reason for exclusion from the group, but more for expansion of the group, so that sufferers of the new condition are accepted.
 - These new members attract others with their same condition (corroborative and experiential bias) and may garner more attention in the media (humanisation effect).
 - When there are sufficient new members all complaining of the same (new) condition, the new condition is accepted as being linked to implants in the same way was conditions or complaints originally.
- Appeals from class-action lawsuits for more women with similar complaints developed after having implants
 - “360 000 women cannot be wrong...”
- Media appeals for women to tell their story
 - “Why not tell YOUR story?”

- **Group polarisation**
 - Increasing number of diseases linked to implants
 - The desire to be at the centre of the group can lead to exaggeration, to attempt to be more like a 'group member' than anyone
 - All or any of the following increase for the individual and for the group as a whole:
 - Severity of complaint
 - Number of different conditions caused by implants
 - Lack of relief from pain or suffering
 - Chronic or degenerative nature of the complaint
 - Also, an increased willingness or desire to accept new group members as having genuine and valid complaints is apparent
 - The willingness or desire to expand the focus of the group, to speak on behalf of others increases, as does the suggestion to non-members that they might too be suffering.
 - Media reports focus on more extreme cases
 - More newsworthy
 - Greater personal loss or tragedy (humanisation effect)
 - Refusal to accept the IOM scientific study
 - Membership of the group more important than facts
 - Continued campaigns call the scientists from the IOM 'liars', and accuse them of working with the manufacturers
 - More claims on the fund in 2006 (360 000) than when fund initially collapsed in 1995 (250 000) despite a conclusive study affirming no link completed in 1999

- **Negative bias**
 - Throughout
 - Wherever there appears to be a conflict between positive and negative information, the negative is always preferred.
 - There is no evidence of a lack of safety, only a lack of evidence of safety.
 - There is no reason to worry, but there is a ban.
 - The ban is lifted, but compensation payouts still continue.
 - Whilst it is never sure what causes suffering, it cannot be denied that suffering has been caused.
 - The company cannot decide to pay out on financial grounds alone; they must be complicit.