A Scientific Education:
The Early Discoveries of RNA and DNA Vaccination

This is a story about academic and commercial avarice. As you read it, you will think it is exaggerated or made up. It is not. It is the story about how the discoveries of DNA and RNA transfection and RNA vaccination were invented. It is also a story of repeated abuse.

To begin, Robert W. Malone MD, MS and I have been married 42 years. We met in high school. Please forgive me, if the tone of this letter is angry. It has been a long and tortous journey of repeated financial, and psychological abuse. Even now, THREE decades after, the abuse continues as other take credit for his work and the press (both scientific and lay) refuse to acknowledge his contributions. So yes, I can get worked up over this – I have lived with this amazing mind for decades. I am amazed at how Robert has been able to keep going scientifically despite the hurdles that have been thrown our way – and yet he has. He persists in doing extraordinary research, often without pay and without any institutional support.

I am in the unique position of being a witness to the events involved in how RNA vaccination was invented and developed, and how individuals at a research institution and a corporation conspired to strip a graduate student from the credit he deserved in inventing RNA and DNA vaccination/gene transfer back in 1988.

The story of non-viral gene therapy and genetic vaccination really started when Dr. Robert Malone was a graduate student at the University of California, San Diego (UCSD) and the Salk, Institute (1986 to 1988). Robert had just finished the first two years of Medical school at Northwestern in an MD/PhD program, when he chose to do his PhD graduate work at UCSD and the Salk Institute. The quality of the investigators, particularly the work of Dr. Verma, was what drew him to UCSD/Salk. Before that, he had been a biochem major at UC Davis and had been involved in some major research in the newly discovered HIV virus, as well as tumor cancer biology and retroviruses. He was already on multiple papers/abstracts prior to starting graduate work at UCSD.

At the Salk Institute/UCSD, he did his thesis work under Dr. Inder Verma on RNA structure and DNA/RNA gene transfer. The first realization that DNA in itself can produce an immune response was when Robert began collaborating with a post-doc in Verma's lab by the name of Dr. Daniel St. Louis in 1987. Dr. St. Louis was working on a hemophilia gene therapy model in rabbits using retro-viral transduction techniques. Dr. St. Louis kept having gene expression stop at about two to three weeks post-treatment and he was sure that this loss of gene expression had to do with the promoter he was using. Dr. St. Louis talked with Robert Malone and Robert got obsessed with this puzzle and spent day and night poring over Dan's data, medical texts and journals. Then, he had a brainstorm. What was going on was that immune responses were shutting down gene expression. It had nothing to do with the promoter Dr. St. Louis was using. He presented all of his work and thoughts to Dr. St. Louis. This was the intellectual exercise that led to Robert discovering RNA and DNA vaccines at that time. Note that Robert is acknowledged in the St. Luis paper (St Louis D, Verma IM.

An alternative approach to somatic cell gene therapy. Proc Natl Acad Sci U S A. 1988 May;85(9):3150-4. doi: 10.1073/pnas.85.9.3150. PMID: 3283738; PMCID: PMC280161).

In fact, Robert talked with me extensively about using retroviral vectors for genetic vaccination during this time, but thought that the dangers of retroviral vectors were too great and that the FDA would not allow for this to be licensed. However, this intellectual challenge led to this idea of using DNA and RNA delivery for vaccines. By spring 1988, his ideas about DNA and RNA vaccination were cohesive and formed the basis for the research plan that Vical later developed.

As a witness to what these ideas represented and the timeline of when the ideas and experiments were performed, I know that Robert was obsessed with gene transfer and immune responses long before he went to work for Vical in 1989. Robert's first paper on RNA/cationic liposome transfection (PNAS) (which now has 747 citations) as well as published papers on RNA/DNA/cationic liposome transfection and embryonic transfection, were researched and written in 1988. I even have a journal entry dated in 1988, where I write briefly of Robert's ideas regarding genetic vaccination.

But let's take a step back further in time. In 1980, the Bayh-Dole Act was passed by Congress. It fundamentally changed the nation's system of technology transfer by enabling universities to retain title to inventions and take the lead in patenting and licensing groundbreaking discoveries. It allowed inventors to profit from their patents. It was truly a brave new world in biotechnology.

This was a time of great excitement about the potential of biotechnology and the money to be made by Universities, inventors and venture capitalists alike. Biotech capitalists were looking for new ideas and San Diego was flush with venture capital funding for biotech. Professors were cashing in on deals to consult and sell their intellectual property. One such person was Dr Inder Verma, a powerful scientist at the Salk Institute, with a joint appointment at UCSD. Dr. Verma was also extremely influential at NIH, NIAID and NCI.

Fast forward to 2018, and remember that Dr. Verma has become infamous for his abuse and harassment of post docs and employees, particularly women. This was due to a large investigation and an article in Science Magazine about his serial sexual misconduct and harassment of those under him, abuse that went on for decades ("*Famed cancer biologist allegedly sexually harassed women for decades*" Science Magazine, 2018). This abuse includes harassing and stalking long after people left his laboratory, which has been well documented. As one woman interviewed put it, "He's going to hurt me. I need grants." His behavior was to threaten people, if they didn't do what he wanted. As a very important person in science and at NIH, he followed through on these threats.

As Robert was the only graduate student in a 20-person post-doc lab, Robert was very vulnerable to Dr. Verma's harassment. Gender abuse is just one facet of cyclic abusive behavior, and Dr. Verma set up a cycle of abusive behavior towards Robert early on. Examples of the typical workplace behavior included Dr. Verma routinely offering grant applications and papers that he was to review to Robert, with instructions to "read them for ideas." Something Robert refused to do, and was so upset about it, that he spoke to the Salk human resources officer. Which of

course, infuriated Dr. Verma. Not only was nothing was done to stop this predatory behavior by the institution, but they informed Dr. Verma that Robert had complained.
Dr. Verma would also put multiple people on the same project to compete against each other in the lab. Tensions among the post-docs were always high and explosive, with people having to hide experiments, notebooks and data – because of the fear of competition from WITHIN the laboratory. It was not unusual for post-docs to accuse each other of sabotaging experiments. But beyond that, Dr Verma harassed Robert. He threatened that he would kill his career, etc., if he didn't comply with his demands, if he didn't include him on patent disclosures, etc.

Back to the story of RNA/DNA transfection and vaccination… Robert's research had primarily been done at the Salk, although, he was a graduate student at UCSD. Patent disclosures were filed on the RNA transfection/gene transfer technologies, which Dr. Verma and the Salk, as well as UCSD were very excited about -as they saw the commercial potential. But UCSD was also involved, as the early RNA transfection work had been done with frog embryos salvaged from a class at UCSD that Robert was a teaching assistant in.

Attorneys from these two institutions (Salk and UCSD) began fighting, as there was no protocol in place for what to do when a graduate student who worked at both institutions made significant discoveries. Who would own the patent rights for Robert's work? Dr. Verma and the Salk attorney were threatening Robert that they would "ruin" his career or somehow financially punish him if he involved UCSD in the patent applications. The Salk attorneys were furious that Robert had sent patent disclosures to UCSD as well as themselves. The attorney for UCSD was threatening that they would come after Robert financially or even his position of graduate student, if he didn't get the Salk to include UCSD on the patent as an assignee.

While this was going on, Robert had, with Dr. Verma's permission, set up a collaboration with Syntex/Dr. Phil Felgner in January, 1988. To do this, Robert contacted Dr. Felgner and laid out his plans for the use of the cationic lipids for in-vitro mRNA transfection. Other letters that Robert wrote to Dr. Felgner clearly lay out some of the core principles of the experiments, as well as sending him a signed summery of Robert's ideas about in-vitro and in-vivo RNA transfection, using RNA as a drug and ideas around new as to synthesize, as well as stabilizing RNA (this letter is available for viewing, upon request). This summer was also sent to UCSD and Salk lawyers as disclosures. Some months later, the Salk CEO Dr. DeHoffman called Robert into a meeting with Dr. Verma at which Roberrt was accused of having set up a collaboration with Syntex unilaterally and without Dr. Verma's knowledge or approval. In the meeting, Robert described what actually happened. This was that Dr. Tony Hunter had tipped Robert off about Syntax lipids and Inder had approved of the collaboration. Inder denied this - because he was under pressure to run all inventions via the for-profit arm of the Salk (SIBIA). So, Inder lied. Robert went to Tony Hunter about this after and was told "of course Inder lied, what would you expect him to do." Later in 1988, Dr. Felgner shared Robert's ideas with Dr. Jon Wolff and we believe Dr. Felgner expressed these ideas as Felgner's own and didn't credit Robert…

Back to the Salk. This conflict over the patent disclosures went on for months – back and forth. A frothy mix of attorneys and full professors trying to exert influence over who would own Robert's work. Robert was a graduate student, with no status or power within the University structure. Dr. Verma also threatened Robert that he would never graduate and would not be able

to find work once he left the Salk, unless he cut off communication with the UCSD attorney about the patent disclosures. Dr. Verma reiterated that he would see to it, that Robert would not get a NIH/NIAID grant ever, if he left the lab. By all accounts, in the years that followed, this threat was acted upon…

Tensions were high. Robert as a graduate student felt disempowered, harassed and was a pawn in a battle much larger than himself. It was literally not possible for Robert to continue his graduate degree, due to the level of harassment, abuse and threats of lawsuits by the institutions involved. Writing this, it seems unbelievable. But I was there. It happened. I actually kept a detailed journal at the time. We have boxes of data, memos, patents disclosures, drafts, etc. all boxed up and ready to share. I will be glad to send much of this documentation upon request and some of it can be found on the attached documents. These are actually just a portion of the documents I have saved and can send more if, wanted.

Robert went to his UCSD graduate advisor (Dr. Deborah Spector), who was frankly skeptical and dismissive of both his claims of abuse and his research. He was told that he had been warned about Dr. Verma, so this was his fault for going to work for him. Because Inder had a "reputation" for being difficult. This, of course, is a classic "blame the victim" mentality.

His thesis proposal was met with skepticism, as his thinking and research (concerning mRNA 5' and 3' untranslated region interactions) was so far ahead that the committee didn't understand it and couldn't be bothered to take the time to understand it prior to the meeting. The meeting went on for five hours, where he was grilled extensively and it left him shaken. This was the research which has since resulted in thousands of citations. Work that was done at the Salk/UCSD, that opened up a new avenue of research and is now saving the world. The lack of support or even understanding at UCSD was appalling. Then the fact that those who did understand it used his research to further their own agenda without acknowledging his contributions was abusive.

In the end, he stepped away from getting his doctorate, settled for an "all but dissertation," and ended up with a masters before going to work at Vical and then going back to complete medical school. Note that the papers that were published from his work at the Salk/UCSD are critical in understanding RNA expression as well as DNA and RNA vaccination. The first paper published from his graduate work at the Salk entitled, "Cationic Liposome-mediated RNA transfection" (PNAS) has 747 citations alone and that is just the start of the many papers and patents that ended up being published by Vical, but all or the majority of the work had been conducted at the Salk. This work is now considered seminal in the discovery and development of DNA/RNA transfection and as well as the discovery of DNA and RNA vaccination. The paper "Direct gene transfer into mouse muscle in vivo," published in 1990 (but much of the work was done at the Salk) has almost 5,000 citations. The Vical Patent, which has work done at the Salk in it, has 1200 citations. The papers and patents that were published from his period at the period at the Salk/UCSD have approximately 6,300 citations. Yet, he came away from the experience without a PhD due to being threatened by attorneys from both institutions and due to the abuse from Dr. Verma.

At one point in 1988, Robert felt so abused, that he went to the UCSD mental health clinic, who diagnosed him with severe PTSD from the abuse. The mental health professional told Robert that his levels were the same as someone coming back from Vietnam. There are records somewhere at UCSD that diagnosed a student with severe abuse from his thesis advisor/attorneys and yet that information was not disclosed to UCSD human resources. Nor was Robert encouraged to seek outside help from the graduate department in dealing with this. In our 45 years together, I have never witnessed anywhere the level of abuse that Robert endured. I can't describe how much Dr. Verma's abuse affected Robert.

Yes- Robert's seminal research at the Salk Institute and continued at Vical and then after is now saving the world from COVID-19. The patents clearly define the discovery of mRNA transfection and vaccination, as do many of the early papters.

Despite 6,300 citations from his published work during this time (1988-1990), he did not end up with a PhD. As Pfizer, University of Wisconsin (WARF), Vical, Merck and now the University of PA take credit for this work, go back to the data and the written word. Always go to the data. It was the Salk where much of the discoveries happened. Data that clearly show he should have been primary inventor on all those patents that Vical filed. Patents that were generated from the patent disclosures filed at the Salk Institute. Disclosures that the Salk attorneys determined Robert should be the sole inventor on. The patent application from the Salk were withdrawn and Robert never told. Which, of course is against the law and University of California (UCOP) policy. Note that Robert asked to see the application in 1991 and the cover letter to Robert does not even imply that the patent had been abandoned (which it had). The Salk withdrew the patent, knowing that Vical wished to LICENSE the patent. Why did they do that? How much was Dr. Verma (at the time, also a paid advisor to Vical) involved in that decision? But I am jumping ahead of myself again. Back to the timeline.

When Robert decided to leave the PhD program, he took a position at a brand-new company called Vical, Inc. in January 1989. He did this for me, so that I could finish my undergraduate degree, as well as so he could continue his research, before returning to medical school in Sept 1989. The plan was this would be a temporary position (8 months duration). Dr. Phillip Felgner recruited Robert into Vical to continue his research and set up a gene delivery/DNA/RNA program. Robert had already been collaborating with Dr. Felgner, who had supplied him with cationic lipids for his experiments. But Robert had the ideas, designs and experiments for this program. The program came from his bench at the Salk. Dr. Felgner was a chemist, not a molecular virologist. Dr. Felgner then became his supervisor.

Robert was put in charge of molecular biology and then immunology (the only employee in this section being himself), with only ten people at the company. In order to quickly ramp up the program, Dr. Felgner encouraged Robert to bring over all his reagents, plasmids and stocks from the Salk Institute.

The fact that Robert brought over all his research materials, including DNA/RNA constructs, plasmids, reporter genes, cell lines, cationic lipid formulations ("Lipofectin") was why the results came so quickly at Vical, as that initial transfection and DNA/RNA vaccine work was just an extension of what Robert had been working on previously at the Salk Institute. Privately,

Robert has always said that it was like casting pearls before swine, as they had no idea the gift they were given. Later we were told that the reason Vical and Merck never pursued RNA vaccination was because they couldn't make RNA after Robert resigned from Vical.

In early 1989, soon after joining Vical, Robert had been working on in-vivo cationic liposomal transfection and needed to perform blinded rodent studies. Vical did not have animal resources set up yet. Thus, he designed the experiments, made up the plasmids, DNA, RNA and reagents, wrote out directions and sent samples to Dr. Wolff at the University of Wisconsin who injected rats with blinded samples. We still have those lab books, set of directions, etc. Robert had cloned the plasmids (at the Salk institute as well as Vical) and worked up all of the reagents himself, He stocked the Vical lab with his stocks from the Salk, which he had transferred to Vical. Dr. Wolff's role was to perform the animal treatments, as Vical, Inc had yet to set up their animal facilities. As a negative control, Robert had included naked RNA. Later, he designed and performed confirmation experiments with plasmid DNA. Imagine his surprise when the negative control came out positive! They repeated the experiments and the same results were obtained. I have documentation that shows that Robert designed these studies and that he supplied the reagents, which were shipped to Dr. Wolff at University of Wisconsin. I have always wondered why Dr. Wolff was even put on all those patents as he contributed nothing to the intellectual design of those initial experiments. If you look at the pages of research data, and the letters/instructions sent with samples, it is clear who did the work. Robert sent blind samples to Dr. Wolff. These lab books clearly document Dr. Wolff's lack of significant intellectual contribution to this project and that much of the work happened at the Salk Institute. The lab books also document that those first experiments were designed and the regents/RNA came from Robert's bench.

The History after Vical

This history is important, because Dr. Verma, as well as Felgner/Wolf continued to use his influence to negatively impact Robert's academic career. When Robert left Vical in August, 1989, he was threatened with legal action by Vical. Vical's directions to Robert were to not talk about the results to anyone or to continue his research that he had begun at the Salk, if he wanted to avoid legal trouble with Vical. Thus, as Robert was quite intimidated and already traumatized by what happened at the Salk, he did not try to assert his primary role in the initial discoveries. This was also because he felt that there were enough people like Dr. Gary Rhodes at Vical, to ensure his pivotal role in the discoveries would not be overlooked. However, he didn't realize that such people didn't have the power or the guts to stand up for what was right.

Thus, he was shocked when the inventor of DNA vaccines (himself) was not even put on the initial papers published by Merck on DNA vaccination. Even though he had been consulting with Vical scientists and had been involved in the design of the experiments. How did this happen? The story is that Merck bought the technology/patents from Vical and got the data from the experiments. Merck then repeated the experiments under Drs. M. Liu/Ulmer and published without ANY of the researchers from Vical or the Salk who had done the initial work and came up with the ideas. Have you ever heard of where the patent inventors aren't included on the proof

of principle papers? One would say, it just doesn't happen… but it did. Those with the "gold" hold the power in both the corporate and scientific worlds.

Even worse… What happened to those Salk patent disclosures and filed application that Robert wrote, which preceded the Vical patents?

Vical knew they were going to have to license from the Salk, we have planning documents from Vical to that effect. The Salk and Vical patents were filed on the same day at the USPTO (3/21/89) – we know the two institutions were working together. This filing date could not be coincidental. Documents that clearly lay out Vical's knowledge that they had to deal with the issues of the patent application and disclosures that were owned by the Salk. Even worse, in 1991, when Robert inquired about the filing, he was told in the cover letter that the filing date was 3/29/89. They literally lied by falsifying the filing date in the cover letter, as it was the same as the Vical patent filing date. This shows that the Salk and Vical were working together in filing the patents, as the patents were all filed from both institutions on the SAME day.

So, our understanding is that they cut a deal with Dr. Verma shortly after Robert left. Vical hired Dr. Verma as a consultant/advisor to the Vical board (some of the details were written up in a local San Diego newspaper). Then Dr. Verma had the Salk institute quietly abandon the patent application(s) already filed. Yep- those patent disclosures and application were disappeared by the Salk. Despite that the Bayh-Dole act requires that inventors get notified if an assignee decides to not pursue a patent, the Salk never told Robert that they had abandoned the patents. So, Robert was never able to continue those patent applications on his own.

Who profited from this? Dr. Verma, and of course, Vical. But also, Dr. Verma's professional friend Dr. Hostetler, a founder and chief scientific officer of Vical, as well as other investors/founders of Vical. Dr. Verma made his money off of these ideas through his formal role at Vical, which included monetization and we believe, stock options. With this act, the fate of Robert being denied acknowledgment of his primary role in the discoveries was set. When Salk abandoned those patents, Robert was not able to receive any formal credit or financial compensation for his discoveries. Dr. Verma, Dr. Felgner, Dr. Wolff all became rich off of Robert's work, while we, including our child, literally starved during his last two years of medical school and continued to have financial issues throughout the next decade.

In the early 1990s. Vical, Inc. successfully sold the intellectual property to Merck. Vical had altered their business plan based on these early successes of DNA gene therapy/genetic vaccination. In fact, the company had completely switched its business focus to genetic vaccination and gene therapy due to Robert's discoveries. This was not the business plan that it had originally been set-up to do Which was anti**Vi**ral lipid formulations – with Dr. Doug Richman and **cal**citonin analogs – with Karl Hostetler, ergo the name Vi – Cal).

The proof of principle experiments in a murine influenza model were completed and the results were very promising (under the guidance of Dr. Gary Rhodes at Vical). Merck agreed to license the DNA vaccine patent for 30 million, but only if they could repeat the experiments in-house and not cite the Vical researchers for their work. Which is what they did. Merck also used their huge public relations team to promote this new vaccination discovery. They also promoted their

own team headed by Dr. Margaret Liu at the expense of the real researchers (Robert and others at Vical). Merck's early press releases were all about their team and their "discoveries." RNA vaccines were evidently dropped, because of Vical and Merck's inability to make RNA after Robert left.

A deeper delve into that history: Dr. Gary Rhodes and Dr. Suezanne Parker set-up up the mouse model for Merck and trained the Merck staff. Robert had trained and helped Rhodes and Parker to design the original vaccine experiments. Then these initial experiments were literally repeated under the Merck team. This set of experiments was what was published with Dr. Margaret Liu as senior author. The Vical employees involved were left off the paper, including Robert. However, note that on the patents, only Vical affiliates and Dr. Jon Wolf are listed as inventors. No one from Merck is. This is because no one from Merck came up with the ideas, or the proof of principle, only the money to buy them. Robert's name (the person who had the idea and proposed the set of experiments to be performed) was not included on the initial DNA vaccination paper published by Merck. For the non-viral gene therapy paper that was published in Science, Vical designated Wolff as primary author and that was that (Wolff, 1990). Robert was listed as second author. He had no choice in the matter, because he resigned from Vical. Thus, Dr. Wolff was given access to the primary data, RNA constructs, etc and wrote the paper. Dr. Wolff didn't come up with the idea of RNA, DNA gene transfer or vaccination, nor did he design the experiments or make the plasmids in those early experiments. But Wolff did get permission from Vical to write the paper and be the lead author that was eventually published. Robert was listed as second author, despite having done almost all of the primary research, made the RNA, designed the use of luciferase, as well as having the original idea. Robert left Vical in disgust, over Dr. Felgner and Dr. Wolff taking credit for his work, as outlined in his letter of resignation. Robert finished his medical degree in 1991 and then did a pathology internship at UC Davis.

When all the Vical patents were originally written, the order of inventors was Felgner, Malone, Wolff and Verma (which everyone knew was wrong – as the ideas were mostly from Robert). Without telling Robert, while the patents were still applications, Vical changed the order of authorship in 1990-91, so the Robert was almost last in authorship (I believe there are 10 total US patents from this work, all with a priority date of 3/21/1989). That priority date of all those patents is three months after Robert left the Salk Institute. At that time, he was the only person on this project at Vical. Just reflect on that. As the only molecular virologist at Vical – all those issued patents (10+) all had a priority date of March 1989, when Robert was the ONLY employee at Vical on the project.

Robert has contributed more to the basic understandings of non-viral gene (mRNA and DNA) vaccination and delivery technologies than anyone I know. However, Robert has been unable to gain that much funding through Federal sources for work continuing in DNA/RNA vaccination or gene therapy despite having almost 100 papers, book chapters and issued patents. He had NIH grants reviewed by Dr. Felgner rejected. Throughout the years, Dr. Felgner Dr. Wolff, Dr. Ulner and Dr. Lieu continued to inflate their roles as primary inventor of DNA vaccines. While Robert continued to have Vical insist that he could not speak to the topic… At one point, Vical sent Robert a "cease and desist" letter – insisting that he not work in any of the fields that were on the Vical patents. This after, getting the Salk to abandon their patent applications that Robert had filed.

Finally, in 1999 Robert challenged NIH to explain why Dr. Felgner was reviewing his grants, as there was a conflict of interest. After a thorough investigation, NIH agreed that Dr. Felgner was obviously biased against Robert and he was assured that Dr. Felgner would not review his grants in the future. After inventing non-viral gene therapy and both mRNA and DNA vaccination, Robert has never been able to secure funding from NIH for work in this field.

He also had a NIAID official let him know in a phone conversation as to why he was never able to win a grant, even when his scores were very competitive (some of the grants were scored excellent but were still triaged by the NIH administration) and should have been funded. He was told that "someone" up high but outside of NIH had put a block on his ability to get grants. The NIH administrator referenced was told that Robert had "mental health issues," (which outside of the PTSD from the abuse at the Salk, wasn't and isn't true) and therefore, they were not to award him grants. I was there in the room when that conversation happened. We surmise it was Dr. Verma who had told this to NIAID/NIH. No one outside of a few people at UCSD/Salk knew of Robert seeking medical help through the UCSD system, which lead to his diagnosis of PTSD from abuse at the Salk/UCSD. At that point, Robert decided to leave academia (2002) and we have either had our own company or worked for others since. So, basically – all evidence suggests that "Verma's Institution" (the Salk) was directly responsible for Robert not being able to procure NIH grant funding for over a decade after he left the Salk Institute.

The RNA transfection and vaccination research conducted at the Salk was so ahead of its time, that it only NOW recognized thirty plus years later. This work is again being credited to the likes of Dr. Verma, Dr. Wolff and Dr. Felgner or to employees at Merck or Pfizer and now the University of Pennsylvania. The Wiki pages for DNA, RNA vaccination/transfection don't even mention Robert's name. Let me repeat that: WIKI HAS NO MENTION OF ROBERT MALONE. There is no "Wiki page" or Google page for Robert Malone, unlike for Katalin Karikó. This frankly makes me sick. As the Univ of PA pushes for their scientists to win the Nobel and has obviously campaigned her accomplishments tirelessly, I have been absolutely shocked and sickened. As an aside, rumor has it that the Univ of PA put in a nomination for their scientists for the Nobel, but as there is no institution for Robert, so no one put in a nomination for him. So, the joke in this family is that Robert will be the "Rosalind Franklin" of RNA vaccines. If the Nobel is ever given for this technology, it will not to go Robert.

For decades, Robert and I tried everything to get the scientific world to pay attention to mRNA vaccination. We wrote papers, a had patent issued in 2001 for mucosal mRNA vaccination, spoke at conferences to no avail. Robert could not get enough funding to continue to work as a scientist, despite thousands of citations of his work.

Now people who had nothing to do with the actual invention are taking credit for it! Not only that, but Stat news, NY Times, and other big newspapers are writing about Dr. Katalin Karikó as if she invented mRNA vaccines, rather than the very small improvements she has made to the existing technologies. BTW- some mRNA vaccine companies like CureVac, do not even use her added chemical in their mRNA vaccine formulations!

Robert devoted much of his life to moving this technology forward. People like Dr. Verma and

Dr. Felgner, along with companies like Vical and Merck and now the Univ of PA and Moderna and others take credit for his work. It is depressing.

So often, biotechnology companies/academia in the United States control the flow of marketing and scientific information. They decide (based on their own corporate structure), who will and will not get to be authors, the rank of authors or even who gets credit for those ideas published. However, companies dare not exclude individuals who deserve to be on a patent.

Robert has always said that: "the most important thing is the science and saving lives, not who gets credit." But this is beyond who invented what, it is the derailment of a career, the ability to conduct science and a scientific legacy. This is a story about academic theft.

I know that this letter may seem to be over-reaching or over-bearing but please consider it in the light that it was written. For years, I have known the "real" story. I have witnessed the cover up of who the real discoverer and hero of this important scientific and medical breakthrough was. I have seen Robert, one of the few people who could have moved RNA vaccines forward early on, unable to secure funding, or get grant funding due to the actions of the Salk, and/or Vical employees. I have witnessed Robert being explicitly told by Vical attorney's that they would come after him, if he continued work that he started as a graduate student. I hope that you also can understand how disheartening and disturbing it is to see someone be largely unknown by the scientific establishment because of abuses by individuals to secure their own place in the history books, avarice or because of a personal vendetta.

With the mRNA and DNA transfection/vaccination discoveries so long ago, the kudos again are going to others for Robert's discoveries. Robert has likened what has happened to him over the past thirty years as to getting repeatedly intellectually raped. Because in the end, what he suffered through resulted in significant PTSD. It harmed him emotionally. It took him years to recover from what happened while he was a graduate student at the Salk, UCSD and then what happened at Vical. He was abused. It is painful.

I hope that somewhere, someone is just a little ashamed. What happened was wrong and tragic. The events surrounding what Dr. Verma did are criminal, in my opinion. That the Salk aided Dr. Verma in silencing a young scientist is shocking, as well as criminal. That UCSD allowed their attorneys to bully a young graduate student and did nothing to help him deal with Dr. Verma as well as the attorneys from the Salk is also just wrong. But in the end, the behavior of Vical and how they promised Robert that they would license the Salk technology, but then didn't. In fact, Vical paid off Dr. Verma by making him an advisor– and then the patent by the Salk was abandoned without informed Robert.

These events happened.

Sincerely,

Jill

Dr. Jill Glasspool-Malone

Papers and Patents directly derived from Robert W Malone's research

A novel approach to study packaging of retroviral RNA by RNA transfection (Abstract). RW Malone, P. Felgner, I. Verma. RNA Tumor Viruses, May 17-18, 1988. Cold Spring Harbor

mRNA Transfection of cultured eukaryotic cells and embryos using cationic liposomes. Malone RW. Focus. 1989; 11:61-8

DNA and RNA Transfection and Vaccination (Abstract). First Place, Northwestern AOA Research Symposium Competition for Medical Students: 1989.

Cationic liposome-mediated RNA transfection. Malone RW, Felgner PL, Verma IM. Proc Natl Acad Sci (PNAS) U S A. 1989;86(16):6077-81. Cited in 749 articles.

Direct gene transfer into mouse muscle in vivo. Wolff JA, Malone RW, et al. Science. 1990;247(4949 Pt 1):1465-8. Cited in 4,750 articles.

High levels of messenger RNA expression following cationic liposome mediated transfection tissue culture cells. Malone R, Kumar R, Felgner P. NIH Conference: "Self-Cleaving RNA as an Anti-HIV Agent (abstract). Washington, DC June 1989.

Cationic liposome-mediated RNA transfection. Dwarki VJ, Malone RW, Verma IM. Methods Enzymol. 1993;217:644-54. Cited in: 102 articles.

Delivery of exogenous DNA (includes mRNA) sequences in a mammal P Felgner, JA Wolff, GH Rhodes, R Malone, D Carson. Biotechnology Advances 1993: 15 (3-4), 763-763

Lipid-mediated polynucleotide administration to deliver a biologically active peptide and to induce a cellular immune response (includes mRNA). Assigned to Vical, Inc and licensed to Merck. No. 7,250,404, date of issue: 7/31/07 Cited in 105 articles. Priority Date: 3/21/1989.

Lipid-mediated polynucleotide administration to reduce likelihood of subject's becoming infected (includes mRNA). Assigned to Vical, Inc and licensed to Merck. US Pat. Ser. No. 6,867,195 B1. Date of issue: 3/15/05. Priority Date: 3/21/1989.

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DNA (and mRNA) vaccines for eliciting a mucosal immune response. US Pat. Ser. No. 6,110,898, date of issue: 8/29/00. **Cited in 40 articles.**

Expression of exogenous polynucleotide sequences in a vertebrate, mammal, fish, bird or human (includes mRNA) . Assigned to Vical, Inc, licensed to Merck. US Pat. Ser. No. 6,673,776. Date of issue: 1/6/04. Priority Date: 3/21/1989.

Methods of delivering a physiologically active polypeptide to a mammal (includes mRNA). Assigned to Vical, Inc, licensed to Merck. US Pat. Ser. No. 6.413.942. Date of issue: 7/2/02. (cited in 150 articles). Priority Date: 3/21/1989.

Induction of a protective immune response in a mammal by injecting a DNA sequence (includes mRNA). Assigned to Vical, licensed to Merck. US Pat. Ser. No. 6,214,804, date of issue: 4/10/01. Cited in 360 articles. Priority Date: 3/21/1989.

DNA vaccines for eliciting a mucosal immune response (includes mRNA). US Pat. Ser. No. 6,110,898. Inventors: RW Malone and Jill Glasspool Malone. Date of issue: 8/29/00. Cited in 40 articles. Priority Date: 3/21/1989.

Induction of a protective immune response in a mammal by injecting a DNA sequence (includes mRNA). Assigned to Vical, Inc, licensed to Merck. US Pat. Ser. No. 5,589,466. Date of issue: 12/31/96. Cited in 899 articles. Priority Date: 3/21/1989.

Delivery of exogenous DNA sequences in a mammal (includes mRNA). Assigned to Vical, Inc, licensed to Merck. US Pat. Ser. No. 5,580,859. Date of issue: 12/3/96. Cited in 1244 articles. Priority Date: 3/21/1989.

Generation of antibodies through lipid mediated DNA delivery (includes mRNA). Assigned to Vical, Inc, licensed to Merck. US Pat. Ser. No. 5,703,055. Date of issue: 12/30/97. Cited in 419 articles. Priority Date: 3/21/1989.

Cationic liposome-mediated RNA transfection. Dwarki VJ, Malone RW, Verma IM. Methods Enzymol. 1993;217:644-54. Cited in: 88 articles.

Many papers and patents on new cationic lipid formulations for mRNA and DNA delivery for vaccination.

Robert Malone's patents issued cationic lipid formations for use in mRNA vaccinations

Formulations and methods for generating active cytofectin: polynucleotide transfection complexes. US Pat. Ser. No. 5,925,623 7/20/99.

Cationic Transport Reagents. US Pat. Ser. No. 5,892,071 issued 4/06/99.

Polyfunctional cationic cytofectins, formulations and methods for generating active cytofectin: polynucleotide transfection complexes. US Pat. Ser. No. 5,824,812 issued 10/20/98.

Cationic Transport Reagents. US Pat. Ser. No. 5,744,625 issued 4/28/98.

Cationic Transport Reagents. US Pat. Ser. No. 5,527,928, date of issue: 6/18/96.

Papers related to cationic lipid polynucleotide transfection and vaccination (including mRNA)

Electroporation enhances transfection efficiency in murine cutaneous wounds. Byrnes CK, Malone RW, et al. Wound Repair Regen. 2004;12(4):397-403.

Marked enhancement of macaque respiratory tissue transfection by aurintricarboxylic acid. Glasspool-Malone J, …, Malone RW. Gene Med. 2002;4(3):323-2.

Enhancing direct in vivo transfection with nuclease inhibitors and pulsed electrical fields. Glasspool-Malone J, Malone RW. In Gene Therapy Methods: Methods Enzymol. 2002;346:72-91

Cutaneous transfection and immune responses to intradermal nucleic acid vaccination are significantly enhanced by in vivo electropermeabilization. Drabick JJ, Glasspool-Malone J, …, Malone RW. Mol Ther. 2001;3(2):249-55. Cited in 192 articles.

Theory and in vivo application of electroporative gene delivery. Somiari S, Glasspool-Malone J, … Malone RW. Mol Ther. 2000;2(3):178-87. Cited in 345 articles.

Efficient nonviral cutaneous transfection. Glasspool-Malone J, …, Malone RW. Mol Ther. 2000;2(2):140-6. Cited in 138 articles.

Developing dendritic cell polynucleotide vaccination for prostate cancer immunotherapy. Berlyn KA, …, Malone RW J Biotechnol. 1999;73(2-3):155-79

Models of Cationic Liposome Mediated Transfection. Gene Therapy and Molecular Biology. Ahearn A, Malone RW. Vol 4. Gene Therapy and Molecular Biology 1999;4

Cationic lipid-mediated gene delivery to murine lung: correlation of lipid hydration with in vivo transfection activity. Bennett MJ, …, Malone RW, Nantz MH. J Med Chem. 1997;40(25):4069-78

Toxicity of cationic lipid-ribozyme complexes in human prostate tumor cells can mimic ribozyme activity. Freedland SJ, Malone RW, et al. Biochem Mol Med. 1996;59(2):144-53

Considerations for the design of improved cationic amphiphile-based transfection reagents. Bennett MJ, …, Malone RW. Journal of Liposome Research 1996;6(3):545-65

Structural and functional analysis of cationic transfection lipids: the hydrophobic domain. Balasubramaniam RP, …, Malone RW. Gene Ther. 1996;3(2):163-72. cited in 172 articles.

Direct gene tranfer into mouse muscle in vivo. N Shafee, ..., RW Malone, et al. International Journal of Virology 2 (1), 33-38

A flexible approach to synthetic lipid ammonium salts for polynucleotide transfection. MJ Bennett, RW Malone, MH Nantz. Tetrahedron letters 36 (13), 2207-2210

Tfx-50 Reagent, a new transfection reagent for eukaryotic cells. Schenborn E, …, Malone RW, et al. 1995

Appendix of documents that can be forwarded to any interested parties
(contact Jill Malone @ info@rwmalonemd.com or Robert at (240) 315-4394

A. Robert W Malone, MD, MS current CV

B. Cationic Lipid-Mediated RNA and DNA patent application, 1988 submitted by the Salk institute. Primary author: Robert Malone. This patent application and all disclosures were later abandoned by the Salk, without informing Robert. This is shown on the Salk counsel cover letter signed in 1991, where it is not mentioned that this patent had already been abandoned. This occurred after Dr. Verma became a consultant (SAB member) of Vical. The ideas and research of this Salk patent application were the foundation of the Vical patents, with a priority date of 3/21/1989. Three months after Robert left the Salk – and Robert was the ONLY person at Vical at that time, working on this project. Vical promised Robert they would license the patent from the Salk – but instead, the Salk abandoned those applications, literally worth millions of dollars at the time (based on the sale of the Vical patents to Merck, which were licensed for $30 million USD). Then Salk abandoned this patent application and all other disclosures submitted by Robert. There was a clear quid-pro-quo.

C. May 1989, Internal Vical document: Intellectual property meeting agenda showing Salk/Malone/Verma ownership of DNA/RNA Transfection and Vaccination technologies. Discussion of a deal to be worked out between the Salk and Vical. Instead, Verma became a consultant (we believe, based on a newspaper article at the time: a Consultant SAB member, with stock options) and the patent application and disclosures at Vical were dropped.

D. Letter from Dr. Robert Malone to Vical dated 2001. This letter details research done at the Salk prior to his employment at Vical. Attachments were not included from this letter, due to length. It is possible to scan them and send them as a google link, if desired.

E. Letter from Robert to a journalist outlining history in 1990.

F. Xenopus RNA Transfection 1988 Malone Salk Data

G. mRNA Transfection of Cultured Euk Cell - data from 1988 at Salk, written up for Vical 1989

H. Attachments relating to discovery Malone Salk and Vical – These include letters to Felgner from the Robert at the Salk in Jan 1988, whereby Felgner was trying to duplicate Robert's results – to provide quality control – with Robert sending him samples. Patent Disclosures (signed by a witness) from the Salk in 1988. This set of documents also includes patent disclosures from Vical, for work done at the Salk where Phil put himself as an inventor – instead of as a witness.

I. Lab book pages – Malone's lab book from the Salk

J. A novel approach to study packaging of retroviral RNA by RNA transfection (Abstract). RW Malone, P. Felgner, I. Verma. RNA Tumor Viruses, May 17-18, 1988. Cold Spring Harbor

K. mRNA Transfect of Cultured Euk Cell embryos Focus Article 1989 -research from Salk 1988

L. Cationic liposome-mediated RNA transfection by R W Malone, P L Felgner, and I M Verma Molecular Biology and Virology Laboratory, Salk Institute, San Diego, CA 92138.
PNAS August 1, 1989 86 (16) 6077-6081; https://doi.org/10.1073/pnas.86.16.6077

M. Patent Disclosures and Application Mix of Salk/Vical

Vical Documents

M. Expression of Liposomally Delivered Polynucleotide Sequence a mammal. The First of ten patents, which incorporate both ideas and data from the Salk. All ten patents have a priority Date March 1989. The Priority date is less than three months after Robert left the Salk and started at Vical for all of the Vical patents.

N. Analysis of Transfection Conditions Instructions Malone to Wolf. Again, samples and research having been done initially at the Salk. This data clearly showing the intellectual driver for these experiments being Robert, with Wolff doing the vivisection work.

O. First RNA CAT Experiment: Malone designed and send RNA/DNA samples to Wolff to inject. Dr. Jon Wolff did the vivisection and wrote up of RNA transfection experiment results – FAXed back to Vical. In this document, Wolff notes that all RNA and DNA samples were sent to Wolff by Robert. Dr. Wolff did that animal injections, but did not contribute muck, if anything to the design. Note that Vical/Felgner designated Wolff to write up the results for publication, thus ensuring himself as first author on the Science paper.

P. Patent disclosures 2/2/89 (two months after Robert started Vical), Other patent disclosures from June 1989 (note how Dr. Felgner added his name ON TOP of Robert's – after they were submitted), Salk disclosures with Rob as only inventor and abstracts.

Q. Letter to Salk and UCSD from Jill Malone, March 2021

All of these documents can be sent via email/google drive, if so desired. Any discovery done will include a treasure trove of more documentation supporting the above assertions.