Lawsuits on mRNA technology show profit-driven struggle for control over vital scientific discoveries

Part two

Benjamin Mateus and Kevin Reed
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The history of mRNA

With the elucidation of DNA's structure came far more complex questions. How does DNA work, and how are proteins and enzymes manufactured within cells? Part of this answer lay in the discovery of messenger-RNA (mRNA), officially announced in 1961. As with its parent, DNA, it took decades of tedious work and involved countless scientists before the molecular and biochemical processes of mRNA were elucidated. However, no one has been awarded the Nobel Prize for its discovery.

The essay by Matthew Cobb linked in the preceding paragraph provides a comprehensive review of that history. In brief, the technical levels achieved for the time in biochemistry could only provide hints at the presence of mRNA and required "feats of imagination" and an "entirely new way of thinking about gene function."

Fundamentally, the discovery of mRNA was spurred by the need to comprehend how genes functioned at the molecular level; how they created proteins that were essential molecular units for the conduct of life. It wasn't enough to know that DNA contained all the hereditary information. How was it translated into "biological function"? One important insight that Watson and Crick's model offered is that the genetic information was linked to the sequences of base pairs on the DNA molecule.

Earlier work by Jean Brachet and Torbjörn Caspersson in the 1940s had found that protein synthesis occurred in the cell's cytoplasm and not the nucleus where the DNA resided. They also noted that during periods of increased protein synthesis, RNA levels increased. Protein manufacturing didn't occur directly on DNA, so intermediary processes were necessary.

Alexander Dounce, in 1952, working at the Rochester Medical School, observed that the "arrangement of amino acid residues [building blocks of proteins] in a given peptide chain [the precursor of proteins] is derived from the specific arrangement of nucleotide residues in a corresponding specific nucleic acid molecule."

He proposed that DNA served as a template for the synthesis of RNA, which then served as a basis for the synthesis of proteins. In 1957, Francis Crick dubbed this the "central dogma of molecular biology," meaning the transfer of genetic material proceeds from nucleic acid to nucleic acid, or from nucleic acid to protein. The information cannot be transferred back.

Though RNA and associated proteins called ribosomes necessary for protein synthesis had been found, the lack of understanding of the nature and function of these structures led to persistent misconceptions on how genetic information was transmitted. The dominant theory at the time was that for every DNA segment translated, there was a corresponding ribosome for synthesizing a particular protein.

Meanwhile, work throughout the 1950s on bacteria showed a rapid turnover of RNA during infection with phages [a virus that parasitizes a bacterium by infecting it and reproducing inside it], leading to the hypothesis that RNA was synthesized in the nucleus and then transported into the cytoplasm, which integrated with the ribosomes. Additionally, they recognized that RNA-specific nucleotide uracil was a requirement for protein synthesis [and not involved in DNA replication] which only confirmed that the message was being "transcribed" in the nucleus and dispatched to the cytoplasm where it could be "translated."

An early hint of a messenger RNA was provided in 1956 by Ken Volkin and Larry Astrachan, working at Oak Ridge National Laboratory in Tennessee, which came from their work with infecting *E. coli* bacteria with phages. The total amount of RNA in the bacteria didn't change, but a small fraction of the total was made in just a few minutes. Interestingly, the composition of this short-lived RNA was that of the DNA from the infecting phage [or virus].

In 1957-58, at the Institut Pasteur, Arthur Pardee and Jacques Monod showed that when a particular gene coding for an essential enzyme was transferred to the bacteria lacking the gene, within minutes, it produced the enzyme it previously couldn't. The second critical insight made by the team that included François Jacob was that in bacteria containing the genes that were transcribed, an enzyme only turned on when a chemical or substrate was introduced, meaning these genes were repressed, and the inducing agent would allow the product to be formed. They called the "repressor gene" a "cytoplasmic messenger." But how this intricate signaling was made and worked out by the cells remained unknown.

Meanwhile, Francis Crick and Sydney Brenner were not working on the regulatory mechanisms of cellular processes like their Paris counterparts. In Brenner's words, "We essentially were interested in the code."

Then on a fateful day, April 15, 1960, Crick, Brenner, and Jacob met for an informal meeting at King's College, Cambridge, after a conference held in London the day before. Jacob pored over the details of their latest experiment, where they showed that when a particular gene was introduced into a bacterium deficient for that enzyme, it immediately produced high levels of that enzyme. He added that Pardee had shown in an experiment that the gene didn't produce a stable, efficient ribosome but a "transitory messenger molecule" they dubbed "X."

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François Jacob wrote in his autobiography *The Statue Within* that "Francis (Crick) and Sydney (Brenner) leapt to their feet. Began to gesticulate. To argue at top speed in great agitation. A red-faced Francis. A Sydney with bristling eyebrows. The two talked at once, all but shouting. Each trying to anticipate the other. To explain to the other what had suddenly come to mind. All this at a clip that left my English far behind."

Having immediately conceived that the mysterious messenger molecule was a transient messenger RNA would mean the ribosomes are only inert complex molecules that could read any message sent to it through the copied template from the DNA, simplifying and universalizing the function and conservative nature of cells in general. The intuitive breakthrough redirected their efforts in attempting to isolate the elusive mRNA.

They worked at Caltech in Pasadena in the following months using Matt Meselon's "ultracentrifuges" for their experiment. As they had surmised, no new ribosomes were made. Instead, as Cobb wrote in his essay, "A small, transient RNA that had been copied from phage DNA was associated with old ribosomes that were already present in the bacterial host. This was messenger RNA."

As Cobb then correctly notes, other researchers and scientists working on these questions were making similar breakthroughs and would have reached these conclusions around the same time. Robert Risebrough and James Watson had also made isolated mRNA around the same time but then heard Crick and Brenner were moving to publish. Watson hurriedly sent Brenner a telegram requesting they hold the publication of their manuscript so they could jointly publish in *Nature* in May 1961, inaugurating the discovery of mRNA.

Cracking the genetic code, pre-messenger RNA, and the genetic revolution

The discovery of mRNA coincided with work done in 1958 by Marshall Nirenberg and Heinrich Matthaei at the National Institutes of Health, where they not only presented the first demonstration of messenger RNA but took the first step to deciphering the genetic code. The question they were seeking answers to was how DNA directed the expression of proteins.

For its time, it was an impressive genetic engineering feat. Knowing that uracil nucleotide only occurs with RNA, they constructed RNA solely of uracil. They then inserted it into *E. coli* bacteria, which possesses all the machinery for protein synthesis. They then added an enzyme that only degraded the *E. coli's* DNA but preserved all its other functions. In other words, no proteins could be built other than from their synthetic RNA.

They then added one radioactively labeled and 19 unlabeled amino acids to their extracts. Amino acids are the building blocks of proteins. The synthesized protein was radioactively labeled phenylalanine, whose genetic code is three uracil bases in a row. Radioactive labeling of nucleotides [tagging the molecules with a tracer] became widely available in the 1950s, allowing for visualizing and detecting nucleic acids at trace concentrations.

Nirenberg presented his paper in August 1961 at the International Congress of Biochemistry in Moscow, electrifying the assembled scientists. The "coding race" followed in the early 1960s to identify all the codes for the various amino acid sequences, primarily between Nirenberg's group at NIH and Spanish Nobel laureate Severo Ochoa at New York University Medical School.

The genetic code is the rule living cells follow to translate genetic information into proteins. George Gamow, a Soviet-American physicist, had postulated that three nuclide bases were needed to encode 20 standard amino acids used by living cells to build proteins. It is now recognized that translation of the mRNA is conducted by ribosomes using transfer RNA molecules (known as soluble RNA at the time) that read the mRNA three nucleotides at a time and add the specific amino acid dictated for the specific position.

By 1966, Nirenberg and his team, with the collaboration of other scientists recruited to assist with the work at NIH, completed their sequencing of the three nucleotide bases corresponding to their respective amino acids. In 1968, he received the Nobel Prize with Har Gobind Khorana for their studies on amino acids and proteins.

In the early 1970s, biochemists and geneticists recognized that a precursor molecule to mRNA must exist, which was then edited down before the finished version was presented to the ribosomes called a pre-messenger RNA. Much of the work in RNA processing, cellular signaling, and complex splicing proteins came from James Darnell and his collaborators.

According to a review published in *Nucleus* in 2014 on the history of the investigation of pre-mRNA, in 1977, two teams working independently, one led by Phillip Allen Sharp at MIT and the other by Richard J. Roberts at Cold Spring Harbor Laboratory, using electron microscopy found that isolated RNA molecules hybridized to double-stranded DNA by displacing one of the DNA strands. However, the mRNA sequence generated was complementary to multiple noncontiguous DNA regions. [Refer to link *electron microscopy* for images of mRNA and DNA from Phillip Sharp's research team.]

In other words, the actual genes were divided into multiple segments along the DNA. These findings then led to 1) the discovery of "introns" in the DNA of eukaryotic cells, which have well-defined nuclei, 2) the understanding that pre-mRNA had to be modified to a mature form, and 3) the recognition that the transcribing of mRNA and editing functions to create a mature form were independent of each other.

Introns, or intragenic regions, are areas of DNA residing between or within genes. An "exon" is conversely part of a gene that will form a part of the final mature RNA utilized for translation into a protein. In other words, when mRNA is first transcribed, the introns and exons are included as pre-messenger RNA. It then undergoes modification with enzymes that splice them out and become the mRNA previously referenced. For their work, Sharp and Roberts shared the Nobel Prize in physiology and medicine in 1993.

In 1978, Walter Gilbert from Harvard suggested that introns were more than just redundant and unnecessary DNA. Rather, they served as possible hot spots for recombination to form new combinations of exons, facilitating evolutionary pathways. Advances in molecular biology have deduced that introns are integral to the function of eukaryotic cells. The reader is directed to a report published in *Frontiers* by Michal Chorev and Liran Carmel on the function of introns in 2012.

These breakthroughs were fundamental for the rapidly evolving genetic revolution that was underway. The evolving complexity of ascertaining the inner workings of cells also meant the need to broaden the scope of inquiry and design more sensitive and efficient tools in this work that brought in a larger core of scientists and researchers in the modern discipline of biochemistry and genetics.

Gene sequencers and the Human Genome Project

In particular, genomic sequencers became integral to any laboratory used in various research applications. After 1977, with the introduction of Frederick Sanger's DNA sequencer, these instruments became widely used, with the first commercialized in 1986 by Applied Biosystems. Next-generation sequencers that allow for large-scale high-throughput genomic analysis have made sequencing commonplace, including synthesizing these genetic strands.

In 1985, Kary B. Mullis, while working as a chemist at the Cetus Corporation, a biotechnology firm in California, invented the polymerase chain reaction (PCR) technique allowing copying DNA segments and amplifying them and thereby bypassing the excruciatingly laborious process and time-consuming process of "cloning" DNA, growing them in bacteria, finding the right segments again and then growing them further

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until enough was obtained.

Cetus attempted to automate the process and produced a DNA Thermal Cycler prototype. By 1989, the biotechnology firm partnered with Hoffman-LaRoche to develop and commercialize in-vitro human diagnostic products and services based on PCR technology. Roche Molecular Systems would buy Cetus's patent and associated technology for $300 million.

A whole industry surrounding servicing these instruments and manufacturing reagents and disposable materials flourished. Regulatory agencies were established, and standards for their use were formalized.

By the mid-1970s, sufficient advances had been made in combining elements of DNA from different organisms, propelling the field of modern genetics, that the National Academy of sciences had called for a temporary moratorium on all genetic experiments until the ethical issues surrounding such investigations were developed and agreed upon, and could form the basis of the principles of modern genetic engineering.

By the mid-1980s, new techniques for targeting and splicing genes were devised. A recombinant vaccine against hepatitis B was being designed. In 1988 the first genetically modified corn using genes from the bacterium *Bacillus thuringiensis* (Bt corn) appeared on US farms that could increase yields by preventing pest infestation.

Based on these advances, the Human Genome Project was conceived in the 1980s and formally launched in 1990, the world's largest international collaborative biological project. The goal was to identify every base pair in the human DNA. Though declared complete in 2003, only 85 percent of the genome had been mapped. A level "complete genome," 99.7 percent, was achieved in May 2021, with the "final gapless assembly completed in January 2022. During this project, several genes were identified as responsible for certain diseases, opening the path towards genetic engineering to treat these conditions.

And with the growing recognition of the potential therapeutic role DNA and RNA can offer in treating an assortment of diseases, advances in drug delivery systems grew in parallel.

Specifically, lipid nanoparticles can transfer these highly fragile genetic strands into the cell's cytoplasm, where they can be employed to create the necessary protein. This is the basis for the Moderna and Pfizer COVID vaccines. Without the maturation of this technology, the mRNA vaccines would have remained in the realm of experiments and theory.

Work in this field was first described in 1965 and proceeded headlong by the mid-70s when exogenous mRNA delivery into cells was shown to be feasible using liposomes, minute spherical sacs (smaller than even cells) of phospholipid molecules something like microscopic soap bubbles that enclose an aqueous core that can be loaded with a variety of drugs or vaccines or even DNA. Even lipid soluble drugs can be stored within the lipid bilayer membrane.

As figure 9A demonstrates, these liposomes for drug delivery can be quite complex. Conceptually, liposomes are extremely small versions of the capsules that we ingest when taking medication. Once the capsule reaches our stomach, it dissolves and releases the drug. Two layers of such lipids makes up the cell membrane that protects the interior of cells from the outside.

Liposomes attempt to deliver these drugs directly into cells and take advantage of the fact that cell membranes are also composed of lipids and once they fuse with the cell, the drugs contained within the liposomes are released inside the cell. In other words, they allow drugs to reach their targets more uniformly while delivering higher drug levels at the site, such as cancer cells targeted by a particular medication. For example, in 1995, Doxil, or liposomal doxorubicin, became one of the first drugs using this technology to gain approval from the FDA for treating various malignancies and remains in use today.

A variety of liposomes have been developed such as targeted liposomes that contain special molecules that bind to cell receptors and are then transported internally. Cationic liposomes have positively charged lipid bilayers, which we will discuss in short, and are extensively used for the delivery of therapeutic genes.

For the interested reader, the following video published in *News Medical Life Sciences* conceptualizes what lipids are and how they are used to manufacture various liposomal drugs. A phospholipid is made of a hydrophilic head that tends to mix with water and two hydrophobic tails made of fatty acids that repel water. When these phospholipid molecules are exposed to water, they self-assemble into the two leaflets as shown in the figure below.

However, it wasn't until the late 1990s that University of British Columbia scientist Pieter Cullis pioneered pH-sensitive lipid nanoparticle drug delivery. Before this work, the use of lipids to deliver RNA was feasible in experiments involving cells but was quite toxic for lab animals, let alone human subjects.

As a graduate in physics in 1972, Cullis turned his attention to the study of cellular membranes. In an interview last month with Janet Rossant at the MaRS Impact Health 2022, he recounted his early experiences, "Biological membranes are absolutely vital, and we knew so little about them. There are thousands of lipids in biological membranes, and we haven't a clue what they do. Not now, even, for the bulk of them."

After more than a decade of studying and working with these membranes, he was able to design liposomal systems that used acidic pH to destabilize the lipid bilayer and load drugs into their core and then raise the pH to neutral to stabilize them in their spherical shape. The idea behind pH-sensitive liposomes grew from observation that certain enveloped viruses took advantage of the acidic environment of a cell's organs to infect it. Similarly, malignant cells exhibit acidic environments compared to normal tissues.

The basic mechanisms of working with these membranes began to take shape and Cullis shifted to entrepreneurial work by opening a company to produce chemotherapy drugs that could deliver these treatments more precisely to where the drugs were needed.

But such work was not deemed financially beneficial for the corporation. As Cullis recalled, "By the mid-90's, the CEO came to me and said, 'Look, putting these old cancer drugs into liposomes is all very well but I can't raise money on that. I need to be doing gene therapy,' which was coming into vogue at the time, which meant we had to encapsulate DNA or RNA [which are highly charged molecules] into these lipid nanoparticles. That was huge problem."

By way of clarification, a March 2021 article by Ryan Cross in *Chemical & Engineering News*, explained that these lipid nanoparticles used in the COVID vaccines "utilize just four ingredients: ionizable lipids whose positive charges bind to the negatively charged backbone of mRNA, pegylated lipids that help stabilize the particle, and phospholipids and cholesterol molecules that contribute to the particle's structure." However, to arrive at this sophisticated molecule was not straightforward.

Fundamentally, as Cullis has previously explained, the challenges posed by these relatively large microscopically charged DNA and RNA molecules had to be surmounted, including the toxicity associated with these early versions of the liposomes. "There are no cationic lipids in nature, and we knew we couldn't use permanently positively charged lipids because they are so damn toxic," including tearing apart the cell membranes.

As Cross explained in his article, "A solution came from new lipids that were charged only under certain conditions. During the late '90s and through the first decade of the 2000s, Cullis, his colleagues at Inex Pharmaceuticals, and the Inex-spinoff Provita Biotherapeutics developed ionizable lipids that are positively charged at an acidic pH but neutral in the blood. The group also created a new way to manufacture nanoparticles with these lipids, using microfluidics to mix lipids dissolved in ethanol with nucleic acids dissolved in an acidic buffer. When the streams of those

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two solutions merged, the components spontaneously formed lipid nanoparticles, which, unlike the hollow liposomes, were densely packed with lipids and nucleic acids."

Years of experimentation tweaking the composition of lipid nanoparticles often met with failure. As Thomas Madden, CEO of Acuitas Therapeutics who worked at Inex at the time, told Cross, "You can have 50 different ionizable lipids that all deliver effectively to cells in culture, and 49 of them won't work a damn in vivo."

Beside the significant amount of work done to understand how these particles work within cells, there was also important work being done to understand how these particles are transported to their cells.

By the end of the 2000s, Cullis partnered with a company in Boston called Alnylam to use the technology to treat liver disorders with small interfering RNAs. Eventually, work done by Alnylam in 2010 led to a lipid nanoparticle formulation for their small interfering RNA drug, Onpattro, used to treat a rare hereditary disease, which received FDA approval in 2018.

Though Alnylam's particular formulation also worked for mRNAs, it was still clumsy. Around 2015, Moderna began investing their efforts to improve these ionizable lipids. Cross explained, "The team [of chemists] made about 100 ionizable lipids and introduced ester linkages into the carbon chains of the lipids to help make them biodegradable…Tweaking the ratio of the four lipids in the nanoparticles altered the LNPs' [Lipid nanoparticles] distribution in the body."

The former head of infectious disease at Moderna, Giuseppe Ciaramella, told Cross, "The devil is absolutely in the details as far as LNPs are concerned. But once you optimize it for one organ, you change out the mRNA with minimal optimization." Moderna has remained elusive and silent on these developments. But so have Pfizer and BioNTech.

More recently, Alnylam filed a claim in Delaware federal court in March of this year against both Moderna and Pfizer, claiming that the vaccine makers had infringed on its patents in developing the COVID vaccines. In early July, Alnylam was granted its patent that covers "a breakthrough class of cationic biodegradable lipids used to form lipid nanoparticles that carry and deliver" mRNA-based vaccines. Moderna is using its status "under federal law" to claim it has statutory protection and insists that its lipids do not resemble Alnylam's.

mRNA as a therapeutic construct takes shape: the venture capitalists wait in the wings

Certainly, Robert Malone's breakthrough experiment in 1987 to produce a protein by using a lipofectin, a synthetic cationic lipid, as a vehicle to carry synthesized pieces of mRNA and transfer them into mouse cells was a critical piece of the puzzle. However, no one then conceived that producing life-saving mRNA vaccines would have been feasible within two decades.

Indeed, the idea of treating RNA as a drug was a brilliant insight. But such intuitions are not arrived at as a flash of lightning. Instead, they are a byproduct of experience built upon the work of many others that had advanced the science to such an extent that in less than three decades from mRNA's discovery, its use as a therapeutic was being recognized.

Still, much work remained. Only a handful of scientists like Dr. Katalin Karikó worked with RNA during this period. As she noted, RNA was a difficult molecule to work with. Its short life, minuscule amounts of proteins that could be generated, and severe adverse reactions to administering it made many consider it unfeasible. Very few felt mRNA could offer anything meaningful, and funding in the form of grants was difficult to come by to sustain work in such a niche field. Postdocs and benchwork scientists are under constant pressure and must show continued progress, often measured by high-impact publications, to get support from their institutions.

A Hungarian biochemist with extensive experience in lipids and RNA during her postdoc years at the Institute of Biochemistry, Biological Research Centre of Hungary, Karikó moved to the United States with her husband and two-year-old daughter in 1985 after her lab lost all funding. After working at Temple University and the Uniformed Services University of the Health Sciences in Bethesda, Maryland, she was hired by the University of Pennsylvania in 1989 to work on messenger RNA.

As she explained, "I always thought most patients don't actually need new genes. They need something temporary, like a drug, to cure their aches and pains. So, mRNA was always more interesting to me."

Her work proceeded slowly, often dead ends, especially as interest in RNAs rapidly faded. Personal health issues and family matters also took a considerable toll. As to her reason for continuing with her position at UPenn, she explained during an interview with PNAS, "The main reason I stayed … despite the lack of a permanent faculty position, was the enthusiasm of Elliot Barnathan and David Langer for our experiments in mRNA therapeutics matched mine."

While considering her option to continue her research or pursue different work entirely, she met Drew Weissman, an immunologist who had moved to UPenn in 1997 and had been struggling with work on HIV and "getting immune cells to produce vaccines." [See Amanda Keener's article *Just the messenger*from 2018] Karikó suggested he use mRNA, thus beginning a long collaboration.

However, the initial work hit a roadblock as the mRNA triggered a shutdown in protein production. They recognized that one of the underlying nucleosides—the letters in RNA's genetic code—was causing the adverse reaction, but which one?

As they continued their investigation into why mRNA was provoking the immune system, in the early 2000s, Karikó came across a study showing that Uridine, one of the nucleic acids in RNA, appeared to trigger the immune system through activation of Toll-like receptors. They decided to replace their mRNA's uridine with an analog called pseudo-uridine, which, to their elation, reduced the immune response to a manageable level, so it would have a therapeutic effect but not overwhelm and damage the host subject. Karikó said of their discovery, "We realized at that moment that this would be very important and could be used in vaccines and therapies. So, we published a paper, filed a patent, established a company, and then found there was no interest. Nobody invited us anywhere to talk about it, nothing."

Though their studies went unrecognized in 2005 by the scientific community at large, they were of immense significance that would provide a practical solution to discovering novel therapies for diseases that had no treatments. However, it did catch the attention of a select few scientists who would go on to found the biotechnology firms Moderna and BioNTech.

A meeting in 2010 between Derrick Rossi, a stem cell biologist at Harvard University, who pitched the idea behind an mRNA technological startup to Robert Langer, a well-established biomedical engineer from MIT turned entrepreneur, and Noubar Afeya, a venture capitalist, led to a matter of months to the formation of the firm Moderna. The following year they brought on Stéphane Bancel as CEO to help the company build its investors and fanciers ranks. Rossi left the company in 2014 over a bitter dispute over who conceptualized the far-reaching implications of this new technology, but with his founder's shares intact.

Moderna, in the recent lawsuit against Pfizer, refers to its 2010 patent, which bears briefly discussing.

In 2010, at Derrick Rossi's laboratory, he and his postdoc, Luigi Warren, were trying to transfer mRNA into stem cells. They utilized the Karikó and Weissman modification and used 5-methylcytidine, which resembles the RNA cells usually make. They succeeded, quickly filed a patent, and began looking for investors using their modified mRNA with "sweeping potential." However, there was one snag. The work was a copy.

As a 2015 report in *Nature* noted, "Karikó and Weissman's patent

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posed a challenge for Moderna. A 2010 internal report from Flagship Ventures [see Chief Executive Noubar Afeyan], which was nurturing Moderna into existence at the time, states that if scientists could not identify alternatives to pseudo-uridine and 5-methylcytidine, 'our company technology may be limited to licensing IP from UPenn.'" They turned to a variant of pseudo-uridine called 1-methylpseudo-uridine "that seemed to do the trick."

Kariko recalled that at the time, there were "signs that there will be a fierce battle for licensing." Chief executive of Silence Therapeutics, an RNA biotech in London, Ali Mortazavi, said, "There's really no understanding of who owns what, so nobody wants to disclose anything."

As for Karikó and Weissman, they received their patent on pseudo-uridine and the modification of mRNA in 2012, but soon after, UPenn sold the intellectual rights to Gary Dahl, who headed the lab supply company that would become Cellscript. Karikó seeing the writing on the wall, left UPenn in early 2013 and took a position with BioNTech, where she has remained. In 2018, BioNTech partnered with Pfizer to develop mRNA vaccines against the influenza virus. Clinical trials began in late 2019 when work was soon halted due to the outbreak of a novel coronavirus in Wuhan, China.

Conclusion

At the turn of this century, a little more than two decades ago, no one could have conceived of mRNA's seemingly endless potential, which only came to light with the COVID pandemic. While it took four years to bring the modern mumps vaccine to market in the early 1960s, it took a few days after the novel coronavirus' genetic sequence was revealed in early January 2020 for Moderna to manufacture the prototype of the mRNA.

But rather than using the technology to mass produce these on an international scale and use it as an adjunct to begin an elimination/eradication campaign, the vaccines were financialized and used as weapons to promote the policy of "living with the virus." Vaccine nationalism dominated the rollout, leaving low- and middle-income nations in the lurch.

The current legal wranglings involve a struggle between rival corporate interests over which will garner the colossal profits to be derived from the immense potential mRNA offers the world. This potential includes important work being conducted for cancer therapies. Besides COVID, there is ongoing work on vaccines against HIV, tuberculosis, and malaria. Rare inherited diseases that hardly ever received funding are now targeted for mRNA therapy. These examples barely touch the surface.

Cullis recently observed, given the recent successes with the COVID vaccines, siRNA therapeutics, and CRISPR [gene editing] technology, "It is completely revolutionary. We are moving into an era of personalized therapeutics, and I think people should start to realize that. Up to this point, we have been dealing with a one size fits all approach to medicine as if these things are suited to all of us, which they are not."

These advances have far-reaching implications for how medicine can be conceived and delivered. Such focused treatments can be formulated in a matter of days and be affordable.

As evidenced by examining the history of the science behind the discovery of the molecular mechanisms hidden inside cells, it is as absurd to claim a proprietary monopoly on the intellectual insights and scientific techniques for exploiting these mechanisms as it would be to patent oxygen, water or the plants and animals whose consumption sustains human beings. No one owns the natural properties that are the basis for life. The capacity to use these to stave off disease and revolutionize medicine must be taken from these financial parasites' hands and made the property of all humanity.

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