Why Weren’t These Vaccines Put Through the Proper Safety Trials For Gene Technology, Asks a Former Pharmaceutical Research Scientist

Description

I joined Beecham Research Laboratories in 1970 as a pharmacologist/endocrinologist charged with discovering new anti-fertility ‘drugs’. My team came close but ultimately failed in this endeavor but as is the norm in the discovery of pharmaceuticals we made the serendipitous discovery of an anti-inflammatory compound which became a very successful effective-and-safe treatment for the symptomatic relief of patients with chronic degenerative joint diseases. We jested amongst ourselves that drug discovery was “like looking for a needle in a haystack and finding the farmer’s treasure”. To outsiders, it was of course a case of ‘chance favouring the prepared mind’.

Whatever, we knew that only one in several thousand compounds we made would be a successful marketed drug. Safety, of course, was paramount. The pharmaceutical industry was still reeling from the thalidomide disaster and the industry along with Government regulatory authorities worked together to do as much as was possible to avoid such tragedies ever happening again. It was perhaps quite understandable, then, we were ultra-cautious, and I have no doubt that on the faintest whiff of any safety problem we ‘failed safe’ and almost certainly ‘threw the baby out with the bath water on many occasions. The industry and regulatory authorities were obsessed in putting safety over efficacy. Getting a drug through the preclinical and clinical stages of safety testing was not only very expensive but invariably took more than a decade. Patent law was changed to give an extended period for exclusivity to allow for the industry to have any chance of making a return on investment.

Another feature of this period was the industry’s relationship with academia. It wasn’t hostile but there was most definitely a difference between the academic freedoms and independence to do research in universities in contrast to the targeted commercial research carried out by industry. We judiciously chose academics as consultants who were prepared to view the relationship as one of equals, but in general there was no doubt there was an attitude of superiority by the academic community. Coupled with this the industry was seen as a very convenient ‘whipping boy’ by the print and TV media. There was hardly a week when BBC Panorama wasn’t exposing some scandal. Making money by trying to make the sick well was seen as a positively evil objective. Investigative journalism was the way to journalistic stardom. What a contrast to the situation we see today. To all intents and purposes over the

past two years the Government regulatory authorities, academia, mainstream media and industry appear to be sharing the same bed – all very cosy! Gone, it seems to me, are the checks and balances that we had in the 1980s that provided the public with some sense of confidence that the medicines being marketed were both effective and safe. Academics are frequently charged now with having vested interests. Securing grant money for research is now a matter for international consideration. Witness the huge amount of funding our universities now receive from China and the Gates Foundation. Who can blame the sceptics cry of 'follow the money'?

So it was that in 1980 I transitioned into pharmaceutical development and became Director of Safety Evaluation of the newly named Beecham Pharmaceuticals. This grand title – again reflecting the emphasis on safety – at ground level meant managing the toxicology and metabolism/pharmacokinetic departments for a decade. Though a raft of safety studies had been agreed to try to guarantee safety, how was it possible to trust the industry to do these studies in strict accordance with the Government regulatory guidelines? Thus, the implementation of formal inspections by the Government regulatory authorities to monitor Good Laboratory Practice (GLP), Good Clinical Practice (GCP) and Good Manufacturing Practice (GMP). No stone would be unturned during these inspections, and I recall now the many sleepless nights mentally wrestling with the inspectorate from the USA Federal Drug Agency and the U.K. Safety of Medicines Department – now called the MHRA (Medicines Health Regulatory Authority). However, it must be said that though there was most certainly, and rightly, an adversarial atmosphere, there was always a recognition that the joint goal was to provide effective medicines that were safe.

With this background, we come to December 2020, when, under emergency measures, 'vaccines' still in the experimental phase of development were rolled out with much fanfare to immunise the vulnerable population against the new viral disease of COVID-19. The disease, caused by a coronavirus named SARS-CoV-2, had and was still wreaking havoc across the globe – originating in China in late 2019. So, in a matter of weeks and months rather than years and decades, a new drug was being administered to healthy – albeit elderly and or infirm – human beings, to protect (immunise) them should they ever become infected with the virus. If this was something of a surprise, there was also the knowledge that previous attempts to discover effective and safe vaccines against earlier strains of this type of virus, namely SARS-1 and MERS, had failed. Furthermore, historically, coronaviruses in general had not proven to be amenable to conventional vaccine technology.

What then was the explanation for this amazing breakthrough at just the very time it was needed? And it was needed big-time, because an unprecedented strategy of locking up the whole population had been taken by public health and governments all around the world, rather surprisingly, all at about the same time, to deal with the pandemic. The only way out was to vaccinate the whole population – not just the old and infirm as we were first told – with a vaccine that was going to be – had to be – very safe and effective. The answer to their prayers was gene technology. Mention gene technology in former times in connection with growing crops more efficiently and eating the food derived from these crops you would have received a bloody nose from the natural food activists. Why not now? Were we told? Were we asleep? Were we all in awe of the hyperbole of Boris *et al* surrounding the brilliance of British – notably Oxford University – research? Just let's call it a vaccine – everyone knows how safe they are. Conflating brand new and untried technology with safe and reliable traditional concepts – no problem!

But there is a problem. The old concepts of dead or attenuated viruses as vaccines – classical vaccine technology – we have had decades of experience both in their biology and manufacture. Annually the general population are offered ‘flu vaccines – few are concerned about their safety, and rightly. Not too much concern either as to their efficacy, but who cares if they are safe. Surely these new ‘vaccines’ can be considered in a similar manner? No, I am afraid not. These new gene-based ‘vaccines’ are working in a completely novel way – nothing remotely resembling that of traditional vaccines. Given that pharmaceutical companies work competitively it was also somewhat of a surprise they took the same approach of targeting what has been termed the ‘spike protein’ of the SARS-CoV-2 virus. This protein is nasty – sometimes being referred to as a ‘pathogenic protein’ – and is recognised as causing many of the awful pathologies associated with the disease of COVID-19. Logically you would inactivate or at least attenuate this nasty spike protein and develop a vaccine around the attenuated virus. But that’s not what was done. These ‘vaccines’ do not contain any of the offending virus at all but rather the gene sequence that causes the nasty spike protein to be made in the body. We have little idea how much of this nasty protein is produced or for how long it lasts after an injection of the gene sequence. Furthermore, stimulating the body’s own complex biological systems to produce the spike protein will mean that the amount of protein produced will vary from person to person. The idea is that the spike protein produced by the gene encoding it elicits a response by our immune system to produce antibodies directed against the spike. When the wild virus comes along and infects us the antibodies recognise the spike protein and attack it thus preventing its nasty effects. And it does, though as we have since learnt this approach isn’t very good at preventing infection or stopping its transmission. Are we perhaps clutching at straws too in claiming that these ‘vaccines’ are preventing serious disease and death? Have we not learnt anything over the past two years in treating Covid symptoms with conventional therapeutic drugs? It is now known the beneficial effects on antibody production wane after a few weeks and months and there is a need for booster injections – how many per annum? Consequently, they surely cannot be anything like the scientific and medical success that is being claimed by the politicians and the mainstream media. A fantastic rollout maybe, but of a second-rate ‘vaccine’. Back to the drawing board chaps. The Pfizer CEO promises a new ‘vaccine’ tackling the Omicron variant in March. Sounds good but too late and pointless.

Now to the important question as to safety of this new class of ‘vaccines’, which are still in their experimental phase of development. The experiment will in fact not finish until 2023. If the ‘vaccines’ are of limited efficacy their safety profile must be as near perfect as any medicine can be since they are being given to healthy people who *might* become infected. Based on the strategy outlined above you would predict that the spike protein being produced by the gene-based ‘vaccine’ as having a toxicology profile not dissimilar to what is seen when infected by the virus. And indeed, that’s just what the data tell us. The side-effect reporting systems in the USA and U.K. show unequivocally that these “vaccines” are an order of magnitude greater of adverse effects than conventional vaccines. Qualitatively the side effect profile is consistent with what we might expect from our knowledge of the biological (pharmacology and toxicology) properties of the spike protein. To claim that the side effects are rare and mild is highly misleading. They are indeed what one might expect to see in sensitive patients. Then there is the crucial question of what we cannot possibly know at this point – that is of their long-term safety. Again, there are good scientific reasons why these injections might interfere with other vital body systems. It is not good enough to dismiss them as theoretical scaremongering. It is down to the manufacturer and regulatory authorities to address these issues experimentally and to demonstrate there are no reasons to be concerned. In my view, all the regulatory authorities around

the world, including our own MHRA, have failed the general public who would expect that they question every aspect of the safety of medicines, especially when it comes down to the assessment of medicines designed not to treat disease but to prevent disease in otherwise healthy people. When it comes to safety it is surely unacceptable to hide behind 'emergency powers' of Government and indemnifying the manufacturer from causing harm. To all intents and purposes, it looks like a collusion of the Government regulators and the pharmaceutical industry – far removed from the gamekeeper-poacher relationship that I described earlier. Any legal action bought by the public against the MHRA and other regulatory bodies for negligence in conducting their statutory duties would surely be hard to deny.

It seems to me that the regulatory authorities may have considered this new class of medicine as a vaccine and followed the toxicology guidelines for conventional vaccines. But as discussed above, they are not vaccines in the conventional sense. They are injections of a laboratory synthesised gene sequence – what in previous decades we would have called a new chemical entity (NCE). Furthermore, they are being given, not as a single dose, but because of their limited efficacy as repeated injections – called boosters. On the hoof, it seems, it is decided that extra doses must be given. How can this possibly be unless supported by the appropriate safety studies? And how convenient for the worldwide authorities regulating the approval of new medicines that the Centers for Disease Control (CDC) in the USA modified the definitions of vaccine and vaccination – to allow for the new "ways in which vaccines can be administered" – to embrace this new technology that would be previously classed as an NCE. Sorry, but simply changing the definition of the term vaccine to fit the properties of these novel injections doesn't obviate the need to conduct the appropriate studies by which their safety can properly be assessed. That is why I use the term vaccine in quotation marks or simply describe them as injections.

So how would I design a package of studies to assess the safety of these novel 'vaccines'?

Here is a list of preclinical toxicology studies that in my view should have been performed before regulatory authorities gave their approval to the licensing of these novel therapies under the Government emergency powers:

1. Acute toxicity assessment in rodents and possibly pigs to assess the local and intramuscular irritancy. The pig is a very good model for assessing human muscle irritancy.
2. A 14 day repeat-dose study in two animal species at three different dose levels of the active moiety i.e., the spike protein. The objective of these studies would be to achieve a no effect dose level and to identify those organs in the body that would be adversely affected at high doses. In other words, establish the potential target organs of toxicity in the clinical setting.
3. Pharmacology studies in appropriate animal species to establish any possible adverse effects on the normal functioning of the body vital organs. Emphasis being paid on the cardiovascular and blood systems as these had been clearly established as targets of the SARS-CoV-2 virus through the spike protein and its known attachment to angiotensin converting enzyme 2 (ACE2) receptors in exerting its pathological effects.
4. Pharmacokinetic studies to establish the distribution of the gene sequence to other parts of the body following intramuscular injection of the gene sequence and the concentrations of spike protein in the blood after intramuscular injection.

These would have been the minimum of studies carried out prior to any trials in humans. The data from

these studies would determine whether there was a sufficient margin of difference between the dose giving rise to the beneficial immunogenic effect and that causing any adverse effects to justify proceeding with clinical trials. In other words, determine the ‘therapeutic ratio’. As discussed above, this ratio would need to be high considering the medicine would be given to healthy people not patients with disease, when the ratio can be much smaller. These early studies defining the general toxicity of the gene sequence/spike protein would be run concurrently with studies to examine possible adverse effects on genes and chromosomes and on reproductive systems, to examine the potential to adversely affect fertility and embryonic and post-natal development. Since what is being considered is a completely novel approach to stimulating the immune system – recognised in the change in definition of the word vaccine – a systematic study of the potential toxicity on the immune system should have also been carried out. It is not at all clear whether any studies in animals were conducted to examine the potential for carcinogenic, reproductive or immune function toxicities. If these studies have been done we need to know about them.

When any medicine is given approval, the regulatory authority is required to publish the SBA – the Summary of the Basis of Approval – in which all the studies leading to the approval are listed and the main findings from them summarised. An expert report summarising all this data must be prepared. However, under the emergency laws surrounding the pandemic, these new injections were not approved but licensed as experimental medicines so there is no transparency as to the regulatory toxicology studies conducted. All I know of is a pharmacokinetic study submitted to the Japanese regulatory authority in animals which showed that the injected gene sequence encoding for the spike protein was distributed quite widely and well beyond just the immune system at which it was targeted. Quite understandably this has led to more questions than answers with regard to the functional and possible pathogenic outcomes from the presence of the injected gene sequence in other organs such as the ovaries.

There is the possibility that this new class of medicines were classed by the regulatory authorities as conventional vaccines and didn’t undergo the preclinical testing (such as described above) required of new chemical entities. If so, this can only be classed as a huge error of judgement by the Government regulators. I can quite appreciate any legal challenge being made against them. Considering the precautionary principle that has characterised Government actions regarding non- pharmaceutical interventions, the contrast to their approach to this new gene technology is striking. At best, it might be characterised as cavalier, but more bluntly the phrase ‘fast and loose’ comes to mind. But of course, Governments were in a very deep hole and one growing deeper as they doubled-down on the precautionary principles of non-pharmaceutical interventions. Nothing now could be allowed to detract from the narrative of the brilliance of the British scientists in discovering these new medicine, nor the huge accolades heaped on the NHS and the Government for the logistics of rolling them out. But it must be recognised as being a huge gamble. Unfortunately, we will never know whether it is a gamble that has paid off. Considering what we know about the life-cycle of viruses generally and their well-established properties of greater contagion but weakening of their virulency over time as they mutate, it’s not clear to me how much of a real benefit these novel ‘vaccines’ have been. The clinical Phase 3 studies which began as randomised controlled trials have now been unblinded – there is now no control/placebo group. There will be no way of knowing from empirical data whether these ‘vaccines’ have been effective when the trials complete in 2023. And then again there seems to be no consideration being given to the collateral damage caused by the non-pharmaceutical or the side-effects caused by the ‘vaccines’. It’s not difficult to claim success when one chooses to consider just

one side of the equation.

‘Get your booster today’ scream the full-page adverts. There was a time when advertising standards and the law forbade direct advertising of prescription medicines to the consumer – but we are now being told, without any semblance of any doubt or provision of the evidence, that “at least one hundred thousand lives have been saved by the vaccines”. Yet how was it that in the summer of 2020 deaths from or with COVID-19 fell to near zero? Such was the optimism that we were given financial encouragement to ‘eat out to help out’ and not a ‘vaccine’ in sight, let alone anyone injected. That’s not to say virologists had thought the virus had disappeared – respiratory viruses don’t and true to form this one didn’t either. There are fundamental principles of virology – this virus has a self-limiting life cycle, just like all others. That’s how they evolve and survive.

The recognised father of toxicology is the 16th century Swiss physician Paracelsus who famously said: “Solely the dose determines that a thing is not a poison.” He was of course referring to medicines.

No one can yet tell me what the dose is of the active moiety generated in the body by these gene-based ‘vaccines’. If we don’t know the dose, how can we possibly judge the efficacy and importantly the safety of these ‘vaccines’? Is not a degree of hesitancy by some people who are aware of these circumstances completely understandable? NHS frontline staff for example. This is especially so when we have known almost from the start of the pandemic that the risks of serious illness and death is highly stratified according to age and health status.

I have only been addressing the issue of assessing the safety of the gene-based injections which produces the active moiety – the spike protein. The formulation – particularly other constituents of the injection – and manufacture of these injections are other subjects outside my competence to discuss. However, it seems there are also real issues that need to be addressed in these areas. Where are the regulatory authorities in ensuring the principles of good manufacturing practice? The early Phase 2 clinical trials from Pfizer, which led to their emergency approval, have also been subject to very serious criticism. One is left wondering how well the principles of GMP, GCP and GLP have been followed and monitored by the independent regulators.

Overall, to the eye of a professional pharmaceutical drug development scientist, it all looks like the proverbial dog’s breakfast!

In 1990 I returned to the Research side – drug discovery. Biological sciences had undergone a revolution in the 1980s and molecular biology, genetics, proteomics, combinatorial chemistry and high-throughput screening were now poised to make a major impact on the drug discovery process. I was wary. More than once I expressed caution in ditching the old – basically medicinal chemistry and pharmacology – for these much-heralded new technologies. Have technology, will travel – but where to?

As far as new medicines were concerned, the great promise was not realised. Let’s use the technology judiciously and not as an end in itself. Big Pharma, recognising the shortfall of innovative new medicines and profitability, were busy rationalising their R&D organisations and looking to consolidate businesses through merger and acquisitions.

Perhaps this has driven Big Pharma to pursue a new more profitable model based on protecting the

healthy rather than treating the sick? Enter the era of the gene-based ‘vaccines’. The new technologies have had a long and difficult gestation period with several stillbirths. But perhaps their time had come with the ‘unprecedented’ virus from the East. A declared worldwide health emergency demanded a technological response, and it was there in waiting. But have we been blinded and duped by technology and lost sight of the end game of providing safe and effective medicines? Was it a judicious use of the PCR, rapid antigen test technology and information APP technology to drive the test and trace fiasco? Was the gene technology ready to be used in a mass world-wide vaccination programme without a thorough examination of the potential problems of short- and long-term safety of this previously untested technology? In my view, technocracy has trumped the sound principles, established over decades and centuries, of basic medical practice, immunology, virology, pharmaceutical sciences and public health generally. In the process, political democracy, personal freedoms, free speech and choice have been dangerously sidelined and even censored.

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