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Mediziner und Wissenschaftler für Gesundheit, Freiheit und Demokratie e.V. (MWGFD)
Medical Professionals and Scientists for Health, Freedom and Democracy

Ms Emer Cooke
Executive Director
European Medicines Agency (EMA)
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Subject: Reply to your letter dated June 29th 2026 and an annotated bibliography regarding risks and lack of benefit of modRNA COVID-19 vaccination products

Dear Executive Director Cooke,

Thank you for your reply to our request. We fully understand your decision to keep the meeting limited in size and confidential.

However, we find it difficult to believe that the EMA is not already in possession of scientific evidence that could lead to a more critical reassessment of the risk-benefit profile of the COVID-19 modRNA vaccines. The growing body of published research raises serious questions as to whether the risks may outweigh the benefits.

For this reason, we would like to contribute constructively to the discussion. Please find attached a non-exhaustive annotated bibliography of the scientific literature on this topic. We have deliberately selected almost exclusively peer-reviewed original research articles, systematic reviews, and meta-analyses published in reputable scientific journals.

We also wish to inform you that this bibliography will be made publicly available and shared with a selected group of stakeholders and decision-makers. We appreciate that evaluating such a substantial body of evidence requires time and careful consideration. Nevertheless, once you have had the opportunity to review the material, we would be very interested in learning whether it has prompted any reassessment of the current regulatory position.

On a lighter note, we would like to recommend John le Carré's brilliant and bestselling novel *The Constant Gardener*. In the Scribner paperback edition (New York, originally published in 2001 and

reissued in 2019), page 331 contains a passage that seems remarkably relevant to the challenges of institutional transparency:

*“And we should never forget that a good cover-up is a lot harder to achieve than a bad murder. A crime, you can maybe always get away with a crime. But a cover-up is going to land you in jail every time... You cover **this** bit up, then out pops **another** bit. So you cover **that** bit up. Then you turn round and that first bit's showing again. And you turn round again and there's a third bit, just sticking its toe out of the sand over there...”*

We hope that our annotated bibliography will encourage a careful, balanced, and evidence-based reassessment of the available scientific evidence.

With our sincere regards,

Prof. DDr. phil. Harald Walach
Chairman of MWGFD (e.V.)
Medical Professionals and Scientists for Health, Freedom and Democracy

Annotated Scientific Bibliography[1]

Studies Regarding the Side Effects and Problems of the genetic COVID-19 mod-RNA Vaccinations

Presented to Ms Emer Cooke, European Medicines Agency

The absence of proof and the proof of absence are epistemologically asymmetric. While a study showing no effects (a "null result") can do so for various reasons, one of them being the true absence of an effect, there are many other reasons for the absence of an effect, for instance bad design, implicit bias, inadequate sensitivity of the assay, and many more. However, if something is found it has to be critically scrutinized for its methodological soundness. With this in mind, we present here published data which we think are robust indicators that the modRNA vaccinations were not safe and which constitute proof of the famous "black swan" phenomenon, following Sir Karl Popper's rationale: one black swan disproves the sentence "*all swans are white*". One study documenting serious problems disproves the sentence "*COVID-19 vaccinations are safe*". In order to support the safety of COVID-19 vaccinations, none of such findings should be present in the scientific literature. We are presenting several such "black swans".

A good resource is the website of Wouter Aukema, who has analyzed the EUDRA-Vigilance database and listed all the side effects that are present there, including the script he used for analyzing it: https://www.aukema.org/.

In order to assess safety, it is also useful to deal with the purported benefit briefly.

The purported benefit of the vaccination campaign

Watson, O. J., Barnsley, G., Toor, J., Hogan, A. B., Winskill, P., & Ghani, A. C. (2022). Global impact of the first year of COVID-19 vaccination: a mathematical modelling study. *Lancet Infectious Diseases*. https://doi.org/10.1016/S1473-3099(22)00320-6

This study is normally cited to argue that the vaccinations were beneficial, because it argued that the modeling calculated the vaccinations saved 144 million lives. However, this study is flawed, because the parameters entering the model were wrong, as was shown by:

[1] This bibliography is not exhaustive and covers only prominent studies which have either been published in the peer-reviewed scientific literature or are submitted for publication and are meanwhile available on preprint servers. We are omitting papers regarding the discussion, whether there was a pandemic at all, and a problem necessitating a vaccination campaign in the first place, and restrict ourselves to presenting evidence regarding the vaccinations themselves.

Klement, R. J., & Walach, H. (2023). SEIR models in the light of Critical Realism - a critique of exaggerated claims about the effectiveness of Covid 19 vaccinations. *Futures*, 103119. https://www.sciencedirect.com/science/article/pii/S0016328723000228?via%3Dihub

Evidence that the vaccination campaign did not prevent any deaths and rather increased excess mortality

Ideally, the question, whether COVID-19 vaccines prevent deaths or contribute to them would have to be studied in long-term, blinded, randomized controlled trials. As has been observed by Peter Doshi [Doshi, P. (2020). Will covid-19 vaccines save lives? Current trials aren't designed to tell us. *BMJ*, *371*, m4037. https://doi.org/10.1136/bmj.m4037], the trials that were conducted were not designed to answer this question and by allowing premature unblinding any chance of answering this question by clinical trials was prevented by regulatory bodies, both in the US and in Europe. Therefore, this question has to be studied indirectly. The following studies can shed some light on the question.

Günther, M., Mörl, F., & Rockenfeller, R. (2022). Where Have the Dead Gone? [Opinion]. *Frontiers in Medicine*, *9*. https://doi.org/10.3389/fmed.2022.837287

This study analyzed published data of phase 4 trials and proved, using all-cause mortality data, that the published studies reported number of deaths in their data that are incompatible with overall mortality statistics. This implies that the data were not correctly reported.

Michels, C., Perrier, D., Kunadhasan, J., Clark, E., Gehrett, J., Gehrett, B., . . . Flowers , C. (2023). Forensic analysis of the 38 subject deaths in the 6-Month Interim Report of the Pfizer/BioNTech BNT162b2 mRNA Vaccine Clinical Trial. *International Journal of Vaccine Theory, Practice, and Research*, *3*(1), 973-1008. https://doi.org/10.56098/ijvtpr.v3i1.85

The finding by Günther, Mörl & Rockenfeller (2022) was replicated in this study, using officially submitted data from regulatory trials. Instead of 38 deaths reported, 220 should have been seen, suggesting, again, flawed reporting.

Mörl, F., Günther, M., & Rockenfeller, R. (2023). How Many Deaths Can Statistically Be Attributed to Anti-SARS-CoV-2 Injections? An Analysis of German Health Data from 2021. *International Journal of Vaccine Theory, Practice, and Research*, *3*(1), 1026-1054. https://doi.org/10.56098/s9cjk650

This study used German pharmacovigilance data, cross-checked against insurance data and corrected for general mortality trend and found that in the year 2021 16'817 deaths can be attributed as likely caused by the vaccination campaign. This finding is supported by

Rockenfeller, R., Günther, M., & Mörl, F. (2023). Reports of deaths are an exaggeration: All-cause and NAA-test-conditional mortality in Germany during the SARS-CoV-2 era. *Royal Society Open Science*, *10*, 221551. https://doi.org/10.1098/rsos.221551

Here, a careful mathematical analysis of 20 years' worth of mortality data from Germany found an excess mortality of more than 27'000 for 2021. Subtracting the expected excess mortality of roughly 7'000 for 2021 would support the attribution of around 17'000 deaths to the vaccination campaign in 2021 alone. This is supported by a more recent publication of this group:

Rockenfeller, R., & Günther, M. (2025). Cohort-resolved excess mortality in Germany (2000-2024): Patterns and implications for the SARS-CoV-2 era. *PLoS One*, *20*(10), e0334884. https://doi.org/10.1371/journal.pone.0334884

The study shows that excess mortality after 2021 is mainly driven by birth cohorts aged now 30-39 and over 69 years of age. Using time-lagged cross-correlation, which can be used to assess potential causality it could be shown that this excess mortality is correlated with vaccination uptake. The findings of this group were factually independently replicated by

a) Kuhbandner, C., & Reitzner, M. (2023). Estimation of Excess Mortality in Germany During 2020-2022. *Cureus*, *15*(5), e39371. https://doi.org/10.7759/cureus.39371

b) Kuhbandner, C., & Reitzner, M. (2025). Regional patterns of excess mortality in Germany during the COVID-19 pandemic: a state-level analysis. *Royal Society Open Science*, *12*(11), 250790. https://doi.org/doi:10.1098/rsos.250790

These two studies together showed that a) excess mortality increased by at least two standard deviations over projected estimates from 2021 to 2022 and that it was b) correlated with vaccination uptake, suggesting that vaccinations did certainly not prevent deaths and very likely contributed to excess mortality.

Walach, H., Klement, R. J., & Aukema, W. (2021). Retracted: The Safety of COVID-19 Vaccinations—We Should Rethink the Policy. *Vaccines*, *9*(7), 693. https://doi.org/10.3390/vaccines9070693

Walach, H., Klement, R. J., & Aukema, W. (2021). The Safety of COVID-19 Vaccinations — Should We Rethink the Policy? *Science, Public Health Policy, and the Law*, *3*, 87-99. https://publichealthpolicyjournal.com/the-safety-of-covid-19-vaccinations-should-we-rethink-the-policy/

We had warned early in 2021, using Dutch pharmacovigilance data and a large cohort study and calculating the Number Needed to Vaccinate, that the harm to benefit ratio of COVID-19 vaccines was bad regarding the prevention of death. We calculated that at most 6 deaths can be prevented by 100'000 vaccinations, likely incurring 4 or more deaths as a consequence, not taking into account other side effects. This study was criticized on the basis that pharmacovigilance data are too weak. But we confirmed the results using regulatory trial data in

Walach, H., Klement, R. J., & Aukema, W. (2022). The risk-benefit ratio of Covid-19 vaccines: Publication policy by retraction does nothing to improve it. *Clinical and Translational Discovery*, *2*(1), e35. https://doi.org/10.1002/ctd2.35

Lataster, R. (2026). The causes of Australian excess deaths in 2021, and beyond: An ecological study considering COVID-19, the lockdowns, and the vaccines. *International Journal of Risk & Safety in Medicine*, 09246479261426743. https://doi.org/10.1177/09246479261426743

This study shows that in 4 out of 8 Australian districts there was an excess mortality associated with vaccination uptake.

Lataster, R. (2023). European excess mortality correlates with COVID-19 vaccinations into 2024. *Bulgarian Medicine*, *13*(2), 24-28. https://basa.bg/en/images/Br_02_2023_bulgarska_medicina.pdf

A correlation analysis of European mortality data across Europe and vaccination uptake yields significantly positive correlations for all European countries with correlations of r = .25 to r = .65.

Denhaerynck, K., Mead, N. M., & Wolfinger, R. (2026). Temporal patterns of all-cause mortality among U.S. nursing home residents across COVID-19 vaccination strata, May 2022-June 2023. *Medical Research Archives; Vol 14 No 3 (2026): Vol.14, Issue 3, March 2026*, *14*(3). https://doi.org/10.18103/mra.v14i3.7380

This study, using publicly available Medicare data for nursing homes showed that mortality peaks in nursing homes persisted in partially and fully vaccinated individuals. Time lagged models show that infection peaks leaded rather than followed mortality peaks, showing that vaccinations did not prevent mortality and likely caused them.

Clark, S. A., Rogers, C., Radetich, M., Hulscher, N., Cosgrove, K., Craven, B., . . . Thorp, J. A. (2026). Global Implications of Vaccination and Rising Infant Mortality in the Philippines. *Medical Research Archives*, *14*(4). https://doi.org/10.18103/mra.v14i4.7457

This population level study of national infant mortality statistics in the Philippines suggest that the rise in infant mortality and malformations in birth cohorts born after maternal COVID-19 vaccine uptake is likely associated with this vaccination campaign.

Alessandria, M., Malatesta, G. M., Berrino, F., & Donzelli, A. (2024). A Critical Analysis of All-Cause Deaths during COVID-19 Vaccination in an Italian Province. *Microorganisms*, *12*(7), 1343. https://doi.org/10.3390/microorganisms12071343

This study, using population level data from the Italian province of Pescara, more than 290'000 individuals, using sophisticated models and correction for immortal time-bias showed that vaccinated individuals had an adjusted Hazard Ratio = 2.4 for early mortality, which was also higher for patients with chronic diseases, showing that vaccinations did not protect patients but rather contributed to mortality. The previous study by Flacco et al (2023), https://www.mdpi.com/2076-393X/11/1/31, did not use this correction and therefore came to false conclusions.

Evidence that the COVID-19 vaccinations contributed to an unacceptable number of serious adverse events

Fraiman, J., Erviti, J., Jones, M., Greenland, S., Whelan, P., Kaplan, R. M., & Doshi, P. (2022). Serious adverse events of special interest following mRNA COVID-19 vaccination in randomized trials in adults. *Vaccine*, *40*(40), 5798-5805. https://doi.org/10.1016/j.vaccine.2022.08.036

This study used regulatory data from Canada and showed that the likelihood to suffer from a serious adverse event following a COVID-19 vaccine was higher than being hospitalized with severe COVID-19.

Mörl, F., Günther, M., & Rockenfeller, R. (2022). Is the Harm-to-Benefit Ratio a Key Criterion in Vaccine Approval? *Frontiers in Medicine*, *9*. https://doi.org/10.3389/fmed.2022.879120

This study used regulatory data to calculate the ratio of serious adverse events due to the vaccinations compared with serious COVID-19 disease. According to common regulatory practice we should see a ratio of one serious side effect for every 10 serious diseases prevented, i.e. a ratio of 0.1. In reality, this ratio was 3.25 for the BioNTech vaccine, 1.1 for the Moderna vaccine, and 0.6 for the Astra Zeneca vaccine. In any case, it was 6 to 30fold over the accepted threshold.

Acuti Martellucci, C., Capodici, A., Soldato, G., Fiore, M., Zauli, E., Carota, R., . . . Manzoli, L. (2025). COVID-19 vaccination, all-cause mortality, and hospitalization for cancer: 30-month cohort study in an Italian province. *EXCLI Journal*, *24*, 690-707. https://doi.org/10.17179/excli2025-8400

This study found a higher cancer incidence in a population level study following COVID-19 vaccinations. At the same time mortality was lower. However, the design of the study does not allow for robust conclusions regarding mortality, as individuals who might have died following the vaccination cannot be documented by its method.

Roh, J. H., Jung, I., Suh, Y., & Kim, M.-H. (2024). A potential association between COVID-19 vaccination and development of alzheimer's disease. *QJM: An International Journal of Medicine*. https://doi.org/10.1093/qjmed/hcae103

These data from the Korean National Health Insurance System shows that the incidence of Alzheimer's and other dementia syndromes are significantly higher in vaccinated individuals.

Mead, M. N., Seneff, S., Wolfinger, R., Rose, J., Denhaerynck, K., Kirsch, S., & McCullough, P. A. (2024). COVID-19 mRNA Vaccines: Lessons Learned from the

Registrational Trials and Global Vaccination Campaign. *Cureus*, *16*(1), e52876. https://doi.org/10.7759/cureus.52876

This review cites a series of studies that contradict the claim that the COVID-19 vaccinations are safe.

Lin, X., Botros, B., Hanna, M., Gurzenda, E., De Mejia, C. M., Chavez, M., & Hanna, N. (2024). Transplacental transmission of the COVID-19 vaccine messenger RNA: evidence from placental, maternal, and cord blood analyses postvaccination. *American Journal of Obstetrics & Gynecology*, *230*(6), E113-E116. https://doi.org/10.1016/j.ajog.2024.01.022

This case series shows that spike proteins from the vaccinations can be transmitted through the placenta to the newborn, contradicting claims that the vaccination products do not enter the blood stream and are safe for pregnant women.

Klement, R. J., & Walach, H. (2024). Commentary: raised c-troponin levels as a sign of myocardial injury after COVID-19 vaccination in healthy individuals are worrying. *The Egyptian Heart Journal*, *76*(1), 16. https://doi.org/10.1186/s43044-024-00441-1

We show that the claim by Buergin et al (https://doi.org/10.1002/ejhf.2978) that cardiovascular damage was higher in cohorts before the vaccination is wrong and based on a selective citation of the literature. This emphasizes that their own finding of 2.8% cardiovascular damage in a well defined cohort after vaccination has to be taken seriously.

Kim, H. J., Kim, M.-H., Choi, M. G., & Chun, E. M. (2024). Psychiatric adverse events following COVID-19 vaccination: a population-based cohort study in Seoul, South Korea. *Molecular Psychiatry*, *29*(11), 3635-3643. https://doi.org/10.1038/s41380-024-02627-0

This study, using the Korean National Health Insurance database, showed that psychiatric disorders such as depression, anxiety disorders, stress disorders and sleep disorders were significantly increased in the vaccinated population, while schizophrenia and bipolar disorders were reduced.

Federico, M. (2024). The Immunologic Downsides Associated with the Powerful Translation of Current COVID-19 Vaccine mRNA Can Be Overcome by Mucosal Vaccines. *Vaccines*, *12*(11), 1281. https://www.mdpi.com/2076-393X/12/11/1281

This study admitted that the modRNA vaccines can create problems by inducing autoimmunity.

Faksova, K., Walsh, D., Jiang, Y., Griffin, J., Phillips, A., Gentile, A., . . . Hviid, A. (2024). COVID-19 vaccines and adverse events of special interest: A multinational Global Vaccine Data Network (GVDN) cohort study of 99 million vaccinated individuals. *Vaccine*, *42*(9), 2200-2211. https://doi.org/10.1016/j.vaccine.2024.01.100

This multinational safety monitoring study confirmed considerable safety signals in COVID-19 vaccines that had been preestablished as potential problems by the WHO for myocarditis, pericarditis, Guillain-Barré syndrome and cerebral venous sinus thrombosis, all of which had been documented by case studies early on.

Yasuhara, J., Masuda, K., Aikawa, T., Shirasu, T., Takagi, H., Lee, S., & Kuno, T. (2023). Myopericarditis After COVID-19 mRNA Vaccination Among Adolescents and Young Adults: A Systematic Review and Meta-analysis. *JAMA Pediatrics*, *177*(1), 42-52. https://doi.org/10.1001/jamapediatrics.2022.4768

Yasmin, F., Najeeb, H., Naeem, U., Moeed, A., Atif, A. R., Asghar, M. S., . . . Waqar, F. (2023). Adverse events following COVID-19 mRNA vaccines: A systematic review of cardiovascular complication, thrombosis, and thrombocytopenia. *Immunity, Inflammation and Disease*, *11*(3), e807. https://doi.org/10.1002/iid3.807

These reviews and meta-analysis found clear evidence of myocarditis and pericarditis and other vascular problems after COVID-19 vaccinations in children and adolescents.

Rhodes, P., & Parry, P. I. (2024). Pharmaceutical product recall and educated hesitancy towards new drugs and novel vaccines. *International Journal of Risk & Safety in Medicine*, *35*(4), 317-333. https://doi.org/10.1177/09246479241292008

This study compares the pharmacovigilance safety signals of various vaccines and drugs that were taken off the market. 37'544 deaths were noted in temporal vicinity to COVID-19 vaccines at the time of accessing VAERS. For Vioxx, recalled 5 years after it went to market, 6'639 deaths were recorded in VAERS, the highest to that date. The authors remark that the recall threshold had long been reached.

Wagenhäuser, I., Reusch, J., Gabel, A., Krone, L. B., Kurzai, O., Petri, N., & Krone, M. (2023). Bivalent BNT162b2 mRNA original/omicron BA.4-5 booster vaccination: adverse reactions and inability to work compared with the monovalent COVID-19 booster. *Clinical ´Microbiology and Infection*, *29*(4), 554-556. https://doi.org/10.1016/j.cmi.2023.01.008

Bivalent BioNTech booster vaccinations resulted in higher number of side-effects compared to mono-valent ones.

Shrestha, N. K., Burke, P. C., Nowacki, A. S., Simon, J. F., Hagen, A., & Gordon, S. M. (2023). Effectiveness of the Coronavirus Disease 2019 Bivalent Vaccine. *Open Forum Infectious Diseases*, *10*(6). https://doi.org/10.1093/ofid/ofad209

The more vaccinations individuals had, the more COVID-19 infections they experienced.

Semmler, A., Mundorf, A. K., Kuechler, A. S., Schulze-Bosse, K., Heidecke, H., Schulze-Forster, K., . . . Ruhrländer, J. (2023). Chronic Fatigue and Dysautonomia following COVID-19 Vaccination Is Distinguished from Normal Vaccination Response by Altered Blood Markers. *Vaccines*, *11*(11), 1642. https://www.mdpi.com/2076-393X/11/11/1642

Halma, M., & Varon, J. (2025). Breaking the silence: Recognizing post-vaccination syndrome. *Heliyon*, *11*(11). https://doi.org/10.1016/j.heliyon.2025.e43478

Ray, U., Schulze Selting, A., Perera, R. P., Yang, Z., Lysenkov, V., Göpel, S., . . . Singh, Y. (2026). Dysregulated NK-cell gene expression defines the enduring symptoms of long COVID-19 [Original Research]. *Frontiers in Immunology*, *Volume 17 - 2026*. https://doi.org/10.3389/fimmu.2026.1720551

COVID-19 vaccinations can induce post-vaccination syndrome, which can be immunologically distinguished from fatigue following natural infection. One striking feature is dysregulation of natural killer cells, which is problematic considering they are the first line of defense against other infections and cancerous cells.

Schmeling, M., Manniche, V., & Hansen, P. R. (2023). Batch-dependent safety of the BNT162b2 mRNA COVID-19 vaccine. *European Journal of Clinical Investigation*, *53*(8), e13998. https://doi.org/10.1111/eci.13998

Manniche, V., Karasak, V., Schmeling, M., Glithorpe, J. D., Fürst, T., & Riis Hansen, P. (2026). Batch-dependent safety signal: Nationwide analysis of suspected adverse events following COVID-19 vaccination in Germany. *International Journal of Risk & Safety in Medicine* https://doi.org/10.1177/09246479261453789

The BioNTech vaccines had different amounts of side-effects, depending on batches. This points to manufacturing problems – see below – which escaped regulatory control.

Salsone, M., Signorelli, C., Oldani, A., Alberti, V. F., Castronovo, V., Mazzitelli, S., . . . Ferini-Strambi, L. (2023). NEURO-COVAX: An Italian Population-Based Study of Neurological Complications after COVID-19 Vaccinations. *Vaccines*, *11*(10). https://doi.org/10.3390/vaccines11101621

This study identified a series of neurological problems following the COVID-19 vaccinations.

Odeh, M., Al-Jussani, G. N., Ashour, A., AlNaqah, H., Hasan, H. A., Sbitan, L., . . . Alhawi, M. (2023). Follow-Up of Side Effects throughout the Entire Course of Coronavirus Vaccination. *Vaccines*, *11*(3), 704. https://www.mdpi.com/2076-393X/11/3/704

Side effects of the vaccinations were frequent, especially in this younger cohort, especially fatigue.

Nakahara, T., Iwabuchi, Y., Miyazawa, R., Tonda, K., Shiga, T., Strauss, H. W., . . . Jinzaki, M. (2023). Assessment of Myocardial 18F-FDG Uptake at PET/CT in Asymptomatic SARS-CoV-2-vaccinated and Nonvaccinated Patients. *Radiology*, *308*(3), e230743. https://doi.org/10.1148/radiol.230743

Even in vaccinated persons without symptoms an inflammation of the heart muscle was visible that persisted up to 180 days.

Li, J.-X., Wang, Y.-H., Bair, H., Hsu, S.-B., Chen, C., Wei, J. C.-C., & Lin, C.-J. (2023). Risk assessment of retinal vascular occlusion after COVID-19 vaccination. *npj Vaccines*, *8*(1), 64. https://doi.org/10.1038/s41541-023-00661-7

Retinal vascular occlusions were observed following COVID-19 vaccinations occurring up to 2 years later.

Gøtzsche, P. C., & Demasi, M. (2023). Serious harms of the COVID-19 vaccines: a systematic review. *medRxiv*, 2022.2012.2006.22283145. https://doi.org/10.1101/2022.12.06.22283145

This systematic review of other reviews and reports found considerable evidence for the presence of Serious Adverse Events of Special Interest after COVID-19 vaccinations.

There are many more publications supporting the unfavorable side-effect profile of the modRNA vaccinations against COVID-19.

There are at least three suspected mechanisms for this. One is the fact that despite the officially propagated narrative the injectable substances did not remain in muscular cells, but were frequently transported in the blood stream to other organs, giving rise to autoimmunological problems, inflammations and related problems such as blood clots, ruptured vessels and circulatory problems. It is interesting to note that the official explanation, for instance on BioNTech's own website and relevant scientific publications explained the principle of modRNA-induced immunity in dendritic cells, not in muscular cells (https://www.biontech.com/de/de/home/pipeline-and-

products/platforms/mrna-platforms.html#mrna-vaccines); see also Sahin et al (2014), referenced below.

The second one is the fact that the production process of the vaccines destined for mass application (process 2) was different from the production process for which regulatory approval was given (process 1). This led to high concentration of residual plasmid-DNA from the production process (process 2) which might create the problem of inclusion of bacterial DNA into the human genome. Apart from that, the cationic lipid nanoparticles which are used for packaging mod-RNA pose themselves a problem. They cannot target specific cells, as is often claimed, but will be randomly distributed in the body and thus target any cell they make contact with. This links up with the fact that the nanoparticles also contain plasmid-DNA. EMA-statements and threshold reference only "free" DNA, but do not consider plasmid-DNA encapsulated in nanoparticles. See the references below.

The third problem has to do with the suppression with innate immunity which is a precondition for modRNA to be taken up by the organism and is inbuilt into that vaccination technology. This leads to a dysregulation of innate immunity. Safe modRNA-vaccines are principally impossible, as the central mechanisms for desired effects and side effects are identical. The production of a protein alien to the body, such as a viral antigen, by cells in the body will lead to attacks of the immune system against the cells presenting these antigens and may escalate into auto-immunity at a later stage.

We present selective evidence for all three of these mechanisms below.

Evidence showing that genetic modRNA vaccination side effects are due to attacks of the immune system against body-cells that present the antigen

Yahi, N., Chahinian, H., & Fantini, J. (2021). Infection-enhancing anti-SARS-CoV-2 antibodies recognize both the original Wuhan/D614G strain and Delta variants. A potential risk for mass vaccination? *Journal of Infection*. https://doi.org/10.1016/j.jinf.2021.08.010

The authors show that antibody-dependent enhancement is relevant for vaccine induced problems, leading to autoimmunity.

Bhattacharjee, B., Lu, P., Monteiro, V. S., Tabachnikova, A., Wang, K., Hooper, W. B., . . . Iwasaki, A. (2025). Immunological and Antigenic Signatures Associated with Chronic Illnesses after COVID-19 Vaccination. *medRxiv*, 2025.2002.2018.25322379. https://doi.org/10.1101/2025.02.18.25322379

The immunological signature of patients suffering from vaccine induced fatigue points towards autoimmune problems as a cause.

Sessa, F., Salerno, M., Esposito, M., Di Nunno, N., Zamboni, P., & Pomara, C. (2021). Autopsy Findings and Causality Relationship between Death and COVID-19 Vaccination: A Systematic Review. *J Clin Med*, *10*(24). https://doi.org/10.3390/jcm10245876

This paper provided an early review of case-studies, many of which reported about vascular and thrombotic problems, and autopsies established causal links.

Mörz, M. (2022). A Case Report: Multifocal Necrotizing Encephalitis and Myocarditis after BNT162b2 mRNA Vaccination against COVID-19. *Vaccines*, *10*(10), 1651. https://www.mdpi.com/2076-393X/10/10/1651

This was one of the first pathological studies of a death following BioNTech vaccinations which established an immunological cause, not due to natural infection, but due to the vaccination, which was causal for the death.

Krüger, U., & Lang, W. (2024). *Geimpft - gestorben: Histopathologischer Atlas der Corona-Impfschäden. Gedenkschrift für Prof. Arne Burkhardt*. Verlag Martin Z. Schröder.

- (2025). *Vaccinated – Dead: Histopathological Findings Following Covid-19 Vaccinations. Memorial Publication for Prof. Arne Burkhardt*. Corage Media.

Although not peer-reviewed, this is a pathological report on autopsies and immunopathology of a series of cases who died after vaccinations. For the majority of cases the vaccination could be established as cause and the mechanism was immunologically mediated inflammation and destruction of tissue, leading to hemorrhages, clots, destruction of the brain-blood barrier and similar problems.

Impurities and DNA/plasmid residues in the drug substances

The molecular analysis of the final product of different batches of modRNA shows a remarkably high amount of small to medium large DNA fragments not only from the linearized DNA template for the spike-coding RNA but also from plasmids and bacterial genomes. This is due to a switch of production process from the PCR-derived DNA template (process 1, original authorization) to a plasmid-derived DNA template (process 2 that was not part of the original authorization). In addition, it was shown that these DNA-plasmids used for DNA template production by Pfizer/BioNTech were derived from the gene therapy program of Pfizer and contain not only the SV40 oncological enhancer gene sequence but, according to an amendment to the EMA [Point 2 in EMA/CHMP/21199/2024], several other regulatory elements from the SV40 virus genome, not necessary for the production process but making the plasmid a shuttle vector which is active in eucaryotic cells and is especially designed to enter the nucleus.

Speicher, D. J., Rose, J., & McKernan, K. (2025). Quantification of residual plasmid DNA and SV40 promoter-enhancer sequences in Pfizer/BioNTech and Moderna modRNA COVID-19 vaccines from Ontario, Canada. *Autoimmunity*, *58*(1), 2551517. https://doi.org/10.1080/08916934.2025.2551517

This paper demonstrates that the modRNA-vaccines by BioNTech and Moderna contain unacceptably high levels of impurities of plasmid DNA residues derived from the mass production process which have not been purified sufficiently.

Kämmerer, U., Schulz, V., & Steger, K. (2024). BioNtech RNA-based COVID-19 injections contain large amounts of residual DNA including an SV40 promoter/enhancer sequence. *Science, Public Health Policy, and the Law*, *v5.2019-2024*(Dec 03). https://publichealthpolicyjournal.com/biontech-rna-based-covid-19-injections-contain-large-amounts-of-residual-dna-including-an-sv40-promoter-enhancer-sequence/

Our group replicated the findings that McKernan's group had previously published on preprint servers, referenced above in all the details.

Thorn CR, Sharma D, Combs R, Bhujbal S, Romine J, Zheng X, Sunasara K, Badkar A. (2022). The journey of a lifetime - development of Pfizer's COVID-19 vaccine. *Current Opinions in Biotechnology*. Dec;78: 102803. https://doi.org/10.1016/j.copbio.2022.102803.

This publication by Pfizer scientific employees confirm, that the basic plasmid selected for Comirnaty-Production was a gene therapy vector: "At Pfizer, we utilized prior plasmid DNA (pDNA) manufacturing technology expertize from Pfizer's Gene Therapy Program2.

EMA/CHMP/21199/2024

Type II variation assessment report EMEA/H/C/005735/II/0202. https://www.ghr.agency/wp-content/uploads/2025/01/Anlage_Wundc_32_Ema_Chmp_21199_2024_Type_Ii_Variation_Assessment.pdf

See point 2: These elements are derived from the backbone of the cloning vector originally used for the generation of plasmid DNA constructs for Comirnaty and include the SV40 sequence elements (SV40 PolyA signal, SV40 Promoter/Enhancer, including SV40 Origin), f1 Origin and TK PolyA terminator.

Dean DA, Dean BS, Muller S, Smith LC. (1999). Sequence requirements for plasmid nuclear import. Experimental Cell Research. Dec 15;253(2):713-22. https://doi.org/10.1006/excr.1999.4716

Here it is shown, that the 72 bp repeats of the SV40 enhancer (found in the Pfizer/BioNTech plasmid remains in Comirnaty) were able to facilitate maximal import of attached nucleic acids into the nucleus of eukaryotic non dividing cells.

Suppression of natural immunity

Sahin, U., Karikó, K., & Türeci, Ö. (2014). mRNA-based therapeutics — developing a new class of drugs. *Nature Reviews Drug Discovery*, *13*(10), 759-780. https://doi.org/10.1038/nrd4278

Ugur Sahin, the owner of BioNTech and developer of its COVID-19 vaccine, published the procedures and the necessity for suppressing natural immunity for the modRNA being taken up by the organism and not immediately being degraded by the first line of immunological defense.

Bakos, T., Mészáros, T., Kozma, G. T., Berényi, P., Facskó, R., Farkas, H., . . . Szebeni, J. (2024). mRNA-LNP COVID-19 Vaccine Lipids Induce Complement Activation and Production of Proinflammatory Cytokines: Mechanisms, Effects of Complement Inhibitors, and Relevance to Adverse Reactions. *International Journal of Molecular Sciences*, *25*(7), 3595. https://doi.org/10.3390/ijms25073595

The lipid-nanoparticles which are used to package the modRNA for transporting it into the organism have themselves no positive regulation for human use. This is likely due to the fact that they are highly inflammatory. The study shows that the complement system is activated by the lipid nanoparticles, which functions like an injection of endotoxin and leads to a release of cytokines as a mechanism of inflammation.

The fact that these vaccinations dysregulate the natural immune system is documented by the following study:

Ray, U., Schulze Selting, A., Perera, R. P., Yang, Z., Lysenkov, V., Göpel, S., . . . Singh, Y. (2026). Dysregulated NK-cell gene expression defines the enduring symptoms of long COVID-19 [Original Research]. *Frontiers in Immunology*, *Volume 17 - 2026*. https://doi.org/10.3389/fimmu.2026.1720551

Marks, A., Siu, S., Bianchini, F., Wang, C., Lakshmi, A., Phelan, M., . . . Brown, B. D. (2026). mRNA vaccine immunity is enhanced by hepatocyte detargeting and not dependent on dendritic cell expression. *Nature Biotechnology*. https://doi.org/10.1038/s41587-026-03099-z

This study shows that any cell can take up modRNA packaged in lipid nano-particles, will express the antigen and thus induce an immune reaction against it. This will, in the long run, lead to attacks of the immune system against the body's own cells and can induce autoimmunity. It certainly means: there is no way of separated desired effects of a modRNA intervention from undesired side effects.

Concluding Summary

Taking these facts and data together we see the following:

1. COVID-19 mod-RNA vaccinations increased overall mortality and did not protect against COVID-19 induced mortality.
2. COVID-19 mod-RNA vaccinations did not protect from severe COVID-19 induced hospitalization. This finding stems from regulatory data and should have given regulators a pause and should have called a halt to the vaccination campaign.
3. There are many severe side-effects that point to immunity directed against the body's own cells as the causal pathological mechanism.
4. The number of deaths and side-effects associated with these vaccines is much higher than that associated with products withdrawn from the market and of other vaccines.
5. This calls into severe doubt the allegedly positive risk benefit rate, since the risk of suffering from death has been established early on as comparable to that of a severe influenza and the risk of other severe side effects was mainly confined to patients with chronic diseases, to multimorbid patients or the elderly. Hence, a general vaccination campaign targeting the general population and indeed children had no scientific basis whatsoever. This is especially severe, because the risk of infection is confined to a minority of individuals being infected and suffering from overt symptoms, while the risk of side-effects is affecting all those who take up the vaccine, which is a much higher percentage than that suffering symptoms of natural infection.
6. The mechanism, by which such side-effects are mediated is immunity due to the fact that the spike protein is expressed by cells of the body which are then attacked by the immune system.
7. In addition, the delivery and the stabilizing of the vaccines within the body requires a temporary suppression of natural immunity which is in and of itself a physiologically and clinically dangerous process.
8. The plasmid residues from the production process which can be found in all types of modRNA vaccines might add additional serious genetic effects to the body cells.
9. modRNA-interventions and delivery of modRNA packaged in cationic lipid nanoparticles will always target any bodily cell they come in contact with, and each cell will express the foreign antigen provoking an immune response against it. This mechanism is responsible both for the desired and undesired effects of such interventions. Hence, a safe modRNA intervention is principally impossible. This was suspected at the outset and should have

counselled precaution. Now we know it, and this should trigger a halt to regulatory approval.

Conjointly this body of data suggests that the statement that there are no scientific data that would call into question the positive risk-benefit ratio of COVID-19 mod-RNA vaccines is scientifically untenable, politically damaging and mocking consumer protection.