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[redacted]

Registered letter delivery

Minister Nina Warken
Federal Ministry of Health

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CC by email: nina.warken@bmg.bund.de

Hamburg, 12 October 2025

Imminent Danger:

Supervisory complaint against the employees of the Paul Ehrlich Institute who are responsible for ensuring that two very large and valid cohort studies are not taken into account in the manner prescribed by law in terms of the drug safety of mRNA and other gene vaccines with regard to significant cancer risks, even though this poses an unprecedented threat to public health in Germany.

Dear Minister,

On 1 July 2025, the so-called Pescara study, a prospective cohort study with almost 300,000 participants – all residents of the Italian province of Pescara aged 11 and above – was published as a peer-reviewed scientific publication. The study investigated whether vaccination with COVID-19 gene vaccines (BioNTech, Moderna, AstraZeneca and Johnson & Johnson; the Paul Ehrlich Institute refers to these as "genetic vaccines") carries an increased risk of cancer. The results were alarming: (among other things) a 54% significantly increased risk of hospitalisation due to breast cancer and a 23% increased overall risk of hospitalisation due to cancer. This means, for example, that one in three vaccinated women diagnosed with breast cancer is affected solely because of one or more gene vaccinations they have received. Overall, one in five cancer patients who have been vaccinated is a victim of previous gene vaccinations, regardless of gender. A summary of this study can be found in my book **GEPRÜFT & BESTÄTIGT (Examined & Confirmed), September 2025 edition**, on pages 170 to 172, which is attached to this letter **(Attachment 1)**.

You can see that the Pescara study is methodologically sound in **Attachment 2** attached here. In addition, a retrospective cohort study from South Korea was published on 24 September 2024, based on data from 8.4 million South Korean health insurance policyholders and confirms the results of the Pescara study with the numerical deviations to be expected due to different lifestyles and country-specific genetics. Details on the Korea study can be found in **Attachment 3**.

In my opinion, there have never been such well-founded cohort studies on drug side effects, and never before has such a high proportion of the population been affected in Germany. Nevertheless, the Paul Ehrlich Institute is not fulfilling its legal obligation to take action. You will find detailed information on the Paul Ehrlich Institute's obligation in this regard in my book **GEPRÜFT & BESTÄTIGT (Examined & Confirmed), September 2025 edition**, on pages 56 to 73, which is enclosed with this letter **(Attachment 1)**.

In addition to the Pescara and Korea studies, another important peer-reviewed study was published on 6 September (Speicher et al. 2025), which demonstrates with impressive breadth and depth what had already been published several times in a simplified form with peer review, namely that mRNA vaccines are heavily contaminated with DNA, which fundamentally carries a cancer risk (**Attachment 5).** A summary of the Speicher et al. 2025 study can be found in my book **EXAMINED & CONFIRMED, September 2025 edition (Attachment 1)**, on pages 159 to 162. As explained in Attachment 5, it generally stands to reason that the massive DNA contamination in mRNA vaccines is the cause of the increased cancer risk found in the Pescara and Korea studies. However, the SV40 promoter enhancer, which is present in very large quantities as a DNA contaminant in Comirnaty, is likely to play a role in particular due to its specific risks of causing cancer in humans. Detailed information on the cancer risk posed by the SV40 promoter enhancer in Comirnaty can be found in **Attachment 4.**

In light of these facts, I hereby lodge a supervisory complaint against the responsible employees of the Paul Ehrlich Institute, who have failed for months now to give the Pescara study the legal validity it deserves.

It is obvious that there is an imminent danger, particularly with regard to mRNA vaccines, in the sense of a very serious and unprecedented threat to public health due to drug side effects, so that immediate action in the form of suspending the authorisations for mRNA vaccines is the only option. Subsequently, a comprehensive investigation must be carried out to determine the extent to which vaccinated individuals have been harmed, and those affected must be informed of how they can obtain redress or compensation. With regard to liability, I would like to point out that the manufacturers are liable for DNA contamination, even if the Federal Republic of Germany has assumed contractual liability for other vaccine damage. In my view, Section 314 of the German Criminal Code (StGB) (poisoning dangerous to the public) applies in this sense, as can be read in my attached book GEPRÜFT & BESTÄTIGT (Examined & Confirmed), September 2025 edition (Attachment 1), pages 255 to 261.

If I do not receive a satisfactory response from you by 10 November 2025, I reserve the right to file criminal charges and further supervisory complaints against all those responsible, including, if necessary, those in your department. Otherwise, you should be aware that the essential facts of the case have already been submitted to the central department of the Chancellery and are therefore also available to the Chancellor's office.

Yours sincerely

Attachments

Attachments

- **Attachment 1**
  Attached separately to this letter:

Geprüft & Bestätigt

DNA-Verunreinigungen im mRNA-Impfstoff Comirnaty von BioNTech und was sie uns sagen

Jürgen O. Kirchner

Gesellschaft, Politik & Medien
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On the quality of the Pescara study

The Pescara study (https://doi.org/10.17179/excli2025-8400) is a rare example of a very large prospective cohort study with nearly 300,000 participants, the entire population of the Italian province of Pescara aged 11 and older, due to the costs and effort involved. This study investigated whether COVID-19 vaccines have an impact on the frequency of hospital admissions due to a cancer diagnosis. The results were published on 1 July 2025:

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Original article:

COVID-19 VACCINATION, ALL-CAUSE MORTALITY, AND HOSPITALIZATION FOR CANCER: 30-MONTH COHORT STUDY IN AN ITALIAN PROVINCE

Cecilia Acuti Martellucci[1,#], Angelo Capodici[1,#], Graziella Soldato[2], Matteo Fiore[1], Enrico Zauli[3], Roberto Carota[2], Marco De Benedictis[2], Graziano Di Marco[2], Rossano Di Luzio[2], Maria Elena Flacco[4], Lamberto Manzoli[1,*]

The Pescara study was conducted by the University of Bologna, with data provided by the local public health service of the province of Pescara. The University of Ferrara was also involved. The study was funded by these institutions, there was no external client or sponsor who could have exerted influence.

The head of the Pescara study, Lamberto Manzoli, is a renowned Italian epidemiologist, public health expert and full professor at the University of Bologna, specialising in epidemiology, biostatistics, public health and health management. He was born in Bologna on 28 October 1971 and holds a doctorate in medicine from the University of Bologna and a Master of Public Health from the Harvard School of Public Health. His academic career includes leadership positions such as Director of the School of Public Health at the University of Bologna, former Director and Vice-Rector at the University of Ferrara, and extensive teaching experience at several leading Italian universities. He has published more than 300 scientific articles, over 27 books or book chapters, and has an H-index of over 58 according to Scopus and 77 in other rankings, with over 17,000 citations. Manzoli's research focuses on preventive medicine, particularly vaccines, epidemiccology of chronic diseases, health care quality assessment, and big data in health care. He has also played key roles in Italian health care institutions and has been instrumental in cancer registries, rare disease networks, and numerous government-funded research projects. He is co-editor of several journals and has contributed to the Oxford Handbook of Public Health Practice. In recognition of his work, Manzoli was awarded the Ferenc Bojan Prize by the European Public Health Association in 2015 and has led high-level research projects for the Italian Ministry of Health.

The ethics vote for the study was granted on 24 March 2020, long before any data on the safety and efficacy of COVID-19 vaccines was available. As the study protocol had to be available for this, it was ensured that it was not dependent on the subsequent discussion of the safety aspects of mRNA technology in particular, but was presented independently and prospectively.

Institutional Review Board Statement

The study was conducted in accordance with the Declaration of Helsinki, and approved by the Ethics Committee of the Emilia-Romagna Region (protocol code 287, approved on 24 March 2020).

Cohort studies:
The premier class among studies on drug side effects

Cohort studies such as the Pescara study are a form of observational longitudinal research in which a group of individuals (cohort) with common characteristics is observed over a certain period of time in order to analyse the influence of exposures (e.g. risk factors or protective factors) on certain outcomes (usually health status or diseases).

Advantages of cohort studies

- Cause-and-effect relationships and temporal sequences between exposures and outcomes can be investigated, which strengthens the basis for causal statements.
- New cases of disease (incidence) can be determined directly, allowing risks and risk factors to be quantified.
- Prospective cohort studies enable precise recording of exposure and reduce the risk of bias through their systematic, forward-looking data collection.
- Multifactorial analyses are possible because different influencing factors can be recorded and evaluated simultaneously.
- Particularly suitable for investigating rare exposures and the long-term effects of lifestyle or environmental factors.

Disadvantages of cohort studies

- Prospective cohort studies are usually very time-consuming and costly. The large amount of personnel and effort required for long-term observation is a significant disadvantage.
- Studies often take many years to produce usable results and are therefore less suitable for rare diseases with low incidence.
- There is a risk of losing study participants (follow-up loss), which can compromise the validity of the results.
- Not always randomised: Groups are not formed at random, which means that bias cannot be ruled out.
- Changes in the medical environment and external factors during the long study period may limit comparability and generalisability.

Cancer registries do not meet the requirements of clinical research in terms of data quality and are therefore not suitable for comparison with cohort studies or even for refuting them.

Data from cancer registries must be interpreted with great caution, as their comparability is limited internationally by numerous factors. Key points of criticism concern both data quality and methodological differences between different countries and cancer registries. In particular, cancer registries do not meet the requirements of clinical research, and international standards of clinical research such as ICH-GCP and legal requirements that define key quality characteristics and processes of clinical research are not applied. Clinical research data must be complete, consistent, accurate and traceable throughout its entire life cycle in order to ensure valid and reliable results – but this is not the case with cancer registries.

Basic requirements for clinical research that are not met by cancer registries

- The data must be accurate, legible, contemporaneous, original, attributable, complete and consistent (ALCOA principle: Attributable, Legible, Contemporaneous, Original, Accurate).
- Any changes, deletions or additions to data must be traceable via an audit trail.
- All processes involved in data collection, storage and evaluation must be documented and validated (including computer-assisted systems).
- Data security and protection against unauthorised access or manipulation must be guaranteed.
- A comprehensive quality management system (e.g. with validated computerised systems, SOPs and CAPA management) is mandatory.
- The scientific validity of data collection must be ensured, including appropriate study design, statistical significance and careful bias assessment.
- The data must be sufficient to assess the safety and benefit of an intervention; this includes quantitative strength, comparability with other procedures and the control of bias and sources of error.
- Regular system and process audits and monitoring to ensure data integrity are essential.

Specific factors that limit the comparability of cancer registries

- The definition, recording and coding of cancer cases is not regulated uniformly worldwide. Different countries use different classification systems, e.g. for the classification of tumour types, tumour stages or therapeutic measures.
- The completeness of registration varies greatly; in some countries, for example, tumour cases are only recorded for inpatient treatment or are missing for certain population groups (e.g. in rural areas).
- The quality of source documentation, the experience of registry staff and the degree of digitisation also play a major role in the recording and validation of data.

Data-specific problems and critical issues in cancer registries

- Registrations based solely on death certificates (DCO) tend to be less reliable and vary greatly from country to country.
- Differences in quality assurance and follow-up affect the accuracy of information on tumour stage or treatment success, for example.
- Due to a lack of standardisation, the period from which data is considered complete may also vary, which can lead to distortions in incidence or survival statistics.

Context and example: Germany

- In Germany, the Cancer Early Detection and Registration Act (KFRG) attempted to standardise the recording and quality of registries nationwide, but regional differences remain.
- Country profiles such as the European Cancer Inequality Register (ECIR) provide information on differences, but also aim to identify systematic deficits and initiate improvements.

Selected specialist publications criticising cancer registry data

Specific literature documenting or discussing deficiencies in data from cancer registries can be found in several relevant publications. These analyse, for example, incompleteness, lack of standardisation, methodological weaknesses, and systemic and process-related problems.

- The article "Cancer Registries: Assessment of the Current Situation" (German, Felix Cornelius 2021, https://pmc.ncbi.nlm.nih.gov/articles/PMC8586842/) discusses structural and content-related deficiencies in detail. It criticises rigid data structures (ADT/GEKID basic data set), a lack of semantic consistency, a lack of dynamism when changes are made, differences in recording practices (e.g. aftercare), a lack of uniformity in data collection and systemic problems of incomplete data.
- Lukas Damerau's thesis in health sciences (2016, https://reposit.haw-hamburg.de/bitstream/20.500.12738/7712/1/BA_Lukas_Damerau.pdf) compares aggregated data from various cancer registries and identifies significant differences and discrepancies between the data sets, indicating shortcomings in the comparability and objectivity of the data.
- In a benefit assessment, the Federal Ministry of Health points to organisational and procedural problems in data collection and processing that lead to deficiencies (2010, https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/5_Publikationen/Praevention/Berichte/Gutachten-Aufwand-Nutzen-Abschaetzung-Krebsregister.pdf).
- Workshops of German experts regularly discuss challenges of data quality and report on recurring anomalies, data errors and interpretation problems, for example at the workshop "Fit for cancer registry data?" (DGEpi/GMDS 2022, https://www.dgepi.de/assets/Arbeitsgruppen/AG-08/2022-05-05_Zusammenfassung_Fit-fuer-Krebsregister daten.pdf).

Key areas of documented deficiencies

- Missing or incomplete reports
- Different recording practices depending on the federal state or registry
- Lack of standardisation and harmonisation (variables, follow-up care, diagnoses)
- Low data completeness and lack of feedback
- Difficult data usage for follow-up scientific projects

Conclusion

In order to make meaningful comparisons of cancer registry data between countries, methodological, organisational and documentation-related peculiarities must be critically taken into account. Differences cannot be attributed solely to medical care or genuine epidemiological effects, but also partly reflect the structure and practices of the respective registries.

Confirmation of the Pescara study by the Korea study

The Korea study (https://pubmed.ncbi.nlm.nih.gov/41013858/), published in September 2025, was conducted in South Korea. It examined the 1-year risk of cancer after COVID-19 vaccination in a very large population group of well over 8 million people. The results identified significant associations between vaccination status, vaccine type and increased cancer risk for certain types of tumours. As this study is based on a very large sample from South Korea's health insurance data covering over 8 million patients, these results are scientifically so valid that they can be considered a general confirmation of the results of the Pescara study (https://doi.org/10.17179/excli2025-8400), which is methodologically even more advanced. However, the Pescara study is far more meaningful, particularly because it was conducted prospectively, whereas the Korea study was retrospective. Unfortunately, the authors of the Korea study did not yet include the results of the Pescara study in their own considerations in their publication of September 2025. With regard to a direct comparison of specific figures from the Korea study with those from the Pescara study, population differences, including lifestyle habits (e.g. diet and long-term cancer incidence), would have to be taken into account. In particular, the incidence of breast cancer in South Korea, at 33 cases per 100,000 women in 2022, is much lower than in Italy, where 120 out of 100,000 women were affected in the same year (based on data from cancer registries, which are generally of limited significance but are appropriate for this purpose).

Study design and methodology of the Korea study

- Large retrospective cohort study based on data from the Korean National Health Insurance Service (2021–2023), involving a total of 8,407,849 subjects.
- Individuals were divided into groups based on their COVID-19 vaccination status.
- Cancer risks were estimated using multivariable Cox regression models and reported as hazard ratios (HR) with 95% confidence intervals.

Main results

- The results are reported as hazard ratios (HR), which reflect the risk of harm:
  HR = 1: Risk is identical in both groups.
  HR > 1: The risk in the study group is **increased** compared to the reference group.
  HR < 1: The risk is **reduced**.
- After one year, significantly increased risks were observed for the following types of cancer:
  - Thyroid: HR 1.351 (95% CI: 1.206–1.514)
  - Stomach: HR 1.335 (95% CI: 1.130–1.576)
  - Colon: HR 1.283 (95% CI: 1.122–1.468)
  - Lung: HR 1.533 (95% CI: 1.254–1.874)
  - Breast: HR 1.197 (95% CI: 1.069–1.340)
  - Prostate: HR 1.687 (95% CI: 1.348–2.111)

Conversion to percentage increase in risk yields the following picture:

  - Thyroid: HR 1.351 → 35.1% increased risk
  - Stomach: HR 1.335 → 33.5% higher risk
  - Colorectal: HR 1.283 → 28.3% higher risk
  - Lung: HR 1.533 → 53.3% higher risk
  - Breast: HR 1.197 → 19.7% higher risk
  - Prostate: HR 1.687 → 68.7% higher risk

- A differentiated look at vaccine type showed an increased risk of thyroid, colorectal, lung and breast cancer for mRNA vaccines.

Authors' conclusions

There are age-, sex- and vaccine-type-dependent associations between COVID-19 vaccination and the occurrence of certain types of cancer after one year in this large Asian population.

Cancer risk Comirnaty: The SV40 promoter enhancer

According to the publication "Quantification of residual plasmid DNA and SV40 promoter enhancer sequences in Pfizer/BioNTech and Moderna mRNA COVID-19 vaccines from Ontario, Canada," published by David Speicher, Jessica Rose and Kevin McKernan in September 2025 (DOI: 10.1080/08916934.2025.2551517), the SV40 promoter enhancer ori DNA sequence was detected only in Comirnaty, BioNTech's mRNA COVID-19 vaccine, and not in the Moderna mRNA vaccine, with amounts ranging from 0.25 to 23.72 ng per dose, as measured by quantitative PCR. The authors calculated that this corresponds to approximately 123 million ($1.^{23\times10^{8})}$to 160 billion (1.60×10^{11}) plasmid DNA fragments per dose carrying the SV40 promoter enhancer and enclosed in the lipid nanoparticles, suggesting a direct transfer of these masses of copies of this DNA sequence into human cells with each vaccination.

The SV40 promoter enhancer is a regulatory DNA sequence from the genome of Simian Virus 40 (SV40), a monkey virus that is frequently used in molecular biological constructs, particularly those for the genetic engineering of specific proteins, to enhance gene expression. SV40 is considered an oncovirus, i.e. cancer-causing, as it can induce tumours in cell cultures under certain conditions.

The SV40 promoter enhancer consists of a DNA sequence called a promoter and another called an enhancer. The promoter initiates the transcription of a gene (the first step in the production of the protein encoded in the respective gene by forming the specific mRNA), while the enhancer amplifies the activity of the promoter, i.e. increases the amount of mRNA product formed. The SV40 enhancer is one of the first examples of such enhancer elements discovered in the genome and can increase the transcription rate of a neighbouring gene by two to twenty times, depending on the activity in different cell types. The SV40 enhancer contains various sequence motifs that are important for the binding of regulatory proteins and the control of gene activity. This structure explains the high activity of the enhancer in different tissue types and species.

The SV40 promoter enhancer is also active in human cells when it enters them. It contains various binding sites for transcription factors that are not limited to viral cells but are also present in mammalian cells and, in particular, in human cells. The SV40 enhancer element can significantly increase the transcription rate of genes in human cells and has therefore been frequently used in plasmid-based expression systems. It has been shown to be active in various human cell types, including B cells, kidney cells and keratinocytes. The effect is particularly pronounced in B cells, where the enhancer can amplify somatic hypermutations (SHM). However, activation has also been observed in other cell types (not only B cells) when the correct transcription factors are present. The SV40 enhancer works by binding and activating transcription factors that are present in almost all cells (including human cells). This enables it to promote the expression of genes linked to it. It has also been shown that the SV40 enhancer can trigger not only an increase in transcription but also mutations, which is relevant for the occurrence of mutation events in certain human cell types.

What is known about the interaction of the SV40 promoter enhancer with human cells comes from laboratory experiments with human cell or tissue cultures. The introduction of these DNA sequences into the cells of living humans has not been documented in the literature prior to the vaccination with Comirnaty. Accordingly, the risk posed by this is completely unexplored and should therefore be assessed with the utmost caution, as anything is possible – especially with regard to the triggering of cancer if the SV40 promoter enhancer sequence is integrated into the DNA of human cells.

Source analysis:
Risks of unintended genetic changes due to the administration of DNA contaminants in parenteral medicines