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France Raises Alarm over 'Very Disturbing' Spike in Sudden Deaths of Babies - News Addicts

Hunter Fielding

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French researchers have raised the alarm over the “abnormal” and “improbably high rate” of sudden deaths among newborn babies in France.

Independent researchers discovered a “very alarming” and “disturbing” spike in newborn deaths in France coinciding with the rollout of vaccines for infants.

French researchers identified possible safety signals in babies coinciding with the rollout of Beyfortus, a recently approved monoclonal antibody treatment for respiratory syncytial virus (RSV) in newborns.

The discovery comes as public health authorities ramp up warnings about the spread of respiratory viruses and step up their promotion of the drug.

In interviews with The Defender, the researchers — French independent scientist and author Hélène Banoun, Ph.D., and French statistician Christine Mackoi — explained that data from France’s National Institute of Statistics and Economic

Studies (INSEE) indicates an improbably high rate of deaths of babies between 2 and 6 days old in France during September and October 2023.

INSEE is the authority that compiles official birth and death data in France.

This increase, the researchers said, coincides with the introduction of Beyfortus in French hospitals, which began on Sept. 15, 2023.

In an interview with cardiologist Peter McCullough, M.D., MPH, Banoun said that over 200,000 newborn babies in France have been injected with Beyfortus since that date.

The Centers for Disease Control and Prevention (CDC) recommended Beyfortus in August 2023, while the European Medicines Agency (EMA) authorized the drug in September 2022.

Beyfortus was developed jointly by AstraZeneca and Sanofi.

The drug is offered as a "one-time shot for infants born just before or during the RSV season and for those less than 8 months old before the season starts," and for some high-risk 8- to 19-month-old infants.

According to The Associated Press, "In the U.S., about 58,000 children younger than 5 are hospitalized for RSV each year and several hundred die."

CNBC reported that "RSV is the leading cause of hospitalization among infants in the U.S." According to the CDC, nearly all children are infected with RSV before the age of 2.

But the French researchers and other medical experts who spoke with The Defender warned that no long-term studies have been

conducted involving Beyfortus and newborns and that the administration of monoclonal antibodies on this population is unprecedented.

They also pointed to data indicating RSV's low risk to babies.

Dr. Meryl Nass, an internist, biological warfare epidemiologist and member of the Children's Health Defense (CHD) scientific advisory committee, told The Defender:

"Giving newborns any drug or biologic should be done with extreme caution, let alone a novel, injected monoclonal antibody.

"You cannot tell if the infant is damaged by the shot, when you don't yet know how healthy the newborn is and how it normally behaves.

"This should be a huge red flag for manufacturers as well as parents."

According to Banoun, "The French government is recommending that Beyfortus be injected into newborns before they leave the maternity ward, from Sept. 15, 2023, even though the product has not been tested on this age group."

Nass pointed out that the CDC published a paper in 2021 on all U.S. RSV deaths over the preceding 12 years. The CDC reviewed death certificates and found there were only 26 deaths per year with RSV, and only 17 deaths per year in the entire U.S. caused by RSV in babies under one-year-old.

According to McCullough, "Among the 22.4 million children under age 5 years, the annual risk of RSV hospitalization is well under 1%."

Sudden deaths among newborns 'alarming,' 'disturbing'

Mackoi told The Defender, “There is an excess of deaths for the months of September and October.

“The excess deaths in October are **very alarming**.

“It is very worrisome that this happened in two consecutive months.”

According to Mackoi, the increase in these sudden deaths coincides with the introduction of Beyfortus in France.

“There is a strong concomitance with the Beyfortus injection since Sept. 15, 2023,” she said.

“In France, babies receive injections of Beyfortus before leaving the maternity hospital.

“They leave the maternity hospital three or four days after their birth …

“These excess deaths are abnormal.”

According to Mackoi, the data show “a 50% increase in deaths of babies between 2 and 6 days of life compared with what would be expected,” noting that “the reference is obtained by dividing the number of deaths by the total number of births in 2018 and 2019; the result is 0.69 deaths between 2 and 6 days per 1,000 births.”

In September, the observed mortality rate was 0.97 deaths per 1,000 births, and in October, it was 1.05 deaths per 1,000 births, Mackoi said.

“It is anomalous that this very significant increase should be found two months in a row.

“It may well be due to the injection of Beyfortus since Sept. 15, 2023.”

“Although of no scientific value, I have received testimonials from relatives and via the internet from families of healthy babies who were hospitalized in intensive care with respiratory distress syndrome immediately after the injection,” Banoun added.

Mackoi said that using the official INSEE data, which she described as “reliable [but] underestimated,” she “calculated for each month, the rate of babies born the month in question and died between 2 and 6 days of life,” and used a Poisson distribution to identify abnormal mortality rates, compiling the findings on her website.

According to the INSEE data, 54 deaths were recorded for 55,489 births in France in September 2023, despite the average number of expected deaths being 38, based on historical averages.

For October 2023, the data showed 61 deaths out of 57,940 births, despite the average number of expected deaths being 40.

Mackoi said that the probability of the September 2023 death figure occurring by chance is 0.9%, while the probability of the increased mortality in newborns in October 2023 is even lower, at 0.1%.

She also noted that “there are no excess deaths less than 48 hours after birth,” and that this is “one more indication” that Beyfortus is causing the deaths because they are not receiving the monoclonal for the first 48 hours of life.

“The coincidence of Beyfortus injections with excess **infant deaths is disturbing**,” Mackoi said.

Monoclonal antibodies may exacerbate symptoms rather than prevent them

These revelations came as the White House announced on Dec. 14, 2023, that it would make 230,000 additional doses of Beyfortus available last month, in addition to 77,000 doses that were released in November 2023.

A study published in the New England Journal of Medicine (NEJM) on Dec. 28 concluded, "Nirsevimab protected infants against hospitalization for RSV-associated lower respiratory tract infection and against very severe RSV-associated lower respiratory tract infection in conditions that approximated real-world settings."

The study was funded by AstraZeneca and Sanofi.

According to Banoun, official data do not indicate that Beyfortus is effective. The data do, however, indicate a high prevalence of adverse reactions — including bronchiolitis — even though the treatment is supposed to protect recipients from respiratory illness.

"The most frequently reported adverse events are upper respiratory tract infections, including bronchiolitis," she said.

Banoun added that data from the French National Authority for Health (HAS) do not "support a possible impact of Beyfortus in terms of reduced length of hospital stay, transfer to intensive care units, and mortality."

"According to HAS, in the trials, the absolute risk of RSV infection was reduced by 3.8% in the five months following injection, and the absolute risk of hospitalization was reduced by 1% to 2% over the same period," she said.

Banoun said the trials were not conducted on newborns, whereas the French government recommends injection from the first days of life in the maternity ward.

According to EudraVigilance, as of Dec. 24, 2023, there were 64 adverse events related to Beyfortus in those 1-month-old or younger, and 68 for those between 2 months and 2 years of age. One death, that of a baby below 1 month old, was recorded, as were 60 records containing the word bronchiolitis.

According to VigiAccess, there were 104 adverse events reported, including 57 infections and respiratory disorders.

Another study, concerning premature babies and newborns suffering from heart or lung disease that compared Beyfortus with monoclonal antibodies previously used on high-risk babies, recorded six deaths — five due to bronchiolitis. Of the six babies that died, five had been treated with Beyfortus.

Yet, "these bronchiolitis cases are not attributed to the treatment by the investigator, who is also the manufacturer of the products," Banoun said.

"All this suggests that nirsevimab [generic name for Beyfortus] could facilitate and aggravate bronchiolitis: these injections take place during periods when the virus is circulating."

"Let's not forget that this whole bronchiolitis 'prevention' campaign is supposed to avoid overcrowding hospitals with babies suffering from the disease," Banoun said.

"If this product doesn't significantly reduce hospital admissions, what's the point?"

According to NTD, "Monoclonal antibodies are copies of an antibody that seek out foreign material to destroy them," but the treatments come with a "risk that the body might trigger a strong reaction to the antibodies."

Complications may be serious and can include “acute anaphylaxis or life-threatening massive allergic reactions and cytokine release syndrome that can result in organ damage.”

This phenomenon is one of the adverse effects of Beyfortus.

In his interview with Banoun, McCullough said, “Antibody-dependent enhancements [ADE] have always been something we’ve been worried about because if antibodies bind the virus but not very tightly, that means they don’t neutralize the virus.

“And then, [a] fragment [Fc] of the antibody binds to a cell receptor.

“In a sense, the antibody can bring the virus into the cell.”

McCullough told The Defender, “The antibodies will invariably affect the development of natural immunity with repeated exposures to RSV during childhood.

“Beyfortus-resistant strains can be expected with indiscriminate use.”

Banoun cited a study in which “two of the 25 subjects in the nirsevimab group with RSV … had an RSV isolate containing substitutions associated with resistance to nirsevimab,” while “No subject in the placebo group had an RSV isolate containing substitutions associated with resistance to nirsevimab.”

Banoun also referred to a September 2022 EMA report, which found that during failed RSV vaccine trials in the past, children died of severe bronchiolitis in the vaccinated groups, but none from the control groups died.

“This ADE is due to the deleterious effect of antibodies which, instead of neutralizing the virus, facilitate its entry into the cell via the receptor of the Fc fragment of immunoglobulins. And it’s

precisely this Fc region of nirsevimab … that industry has seen fit to modify," Banoun said.

"Manufacturers are looking for the beneficial effects of this phenomenon and are wary of deleterious effects, which is why they have investigated the risk of ADE with Beyfortus in animal models," Banoun added. "They claim not to have detected it, but the EMA points out, unmoved, that no histopathological evaluation of rats was carried out after treatment and infection with RSV: This is the only recognized marker of ADE."

On his Substack, McCullough wrote that this effect may be triggered by aerosolized RSV virions present in hospitals.

"This means as ambient aerosolized RSV virions are present in hospitals, clinics, and home, the monoclonal antibody may backfire and enable the inhaled virion to gain access to the bronchial epithelial lining and cause worse bronchiolitis than the baby would have with their own developing natural immunity," he wrote.

Beyfortus was administered on newborns despite being tested on older babies

During the clinical trial leading up to the approval of Beyfortus by the CDC and the U.S. Food and Drug Administration (FDA), a total of 12 infant deaths were recorded.

However, the FDA claimed the deaths were "unrelated" to the antibody.

CNBC reported in June that of the 12 infants, "Four died from cardiac disease, two died from gastroenteritis, two died from unknown causes but were likely cases [of] sudden infant death syndrome, one died from a tumor, one died from COVID, one died

from a skull fracture, and one died of pneumonia."

"Fact-checkers" were quick to respond to any stories indicating that the infants' deaths were related to Beyfortus, with factcheck.org writing in August 2023, "There isn't evidence the [Beyfortus] shots have killed any babies, contrary to social media claims."

However, according to Banoun, "According to the HAS and EMA, 11 deaths were reported in the nirsevimab groups, one death in the pavilizumab (former equivalent drug) group and three deaths in the placebo groups. The FDA counted 12 deaths in all treated groups versus three in the placebo groups, not including the one that occurred after the follow-up period."

"It should be noted that all deaths in the placebo groups concerned premature babies in the Griffin study," Banoun said. "In trials involving full-term babies, all deaths involved treated subjects."

Banoun said:

"The FDA has added one death in the placebo groups which occurred after the end of follow-up, but no mention is made of any deaths in the treated groups which occurred after this same period.

"Similarly, a significant number of babies are withdrawn from the trials and therefore no longer followed up after their withdrawal.

"This imbalance is therefore potentially more serious than published."

Other studies also showed infant deaths connected to Beyfortus.

McCullough told The Defender, "I am concerned about 3 versus 0 deaths with Beyfortus and placebo respectively in the MELODY

trial published in NEJM, 2022."

Nass pointed out another such anomaly in clinical trial results where "The deaths were said to be disproportionate between the placebo and nirsevimab groups."

"I don't trust the data as being reliable," Nass said, "For instance, in this NEJM-published trial, 9.5% of babies who did not receive nirsevimab wound up with pneumonia and 'lower respiratory tract' RSV infections."

"This seems awfully high," Nass continued, "Especially when the CDC's own study showed only 17 babies per year die from RSV. I find it hard to rely on the NEJM data."

"The problem is that, with potentially billions of dollars riding on the outcome of a few clinical trials, there may be tremendous pressure to come up with the desired results. And there are many ways in which the desired results can be achieved," she added.

Banoun also pointed out that while Beyfortus is administered to newborns, clinical studies tested the drug on older babies.

If we refer to the descriptions of the deceased babies, in the Domachowske study, "Only 1 was less than a month old at the time of injection (23 days), while all the others were between 1 and 7.5 months old," she said. "We find the same panel of babies in all the other studies … in the Griffin study, the babies have a median age of over 6 months, in the Hammitt and Domachowske studies, only half the babies are under 3 months old … in the Hammitt study, the median age is 2.6 months (range 1.05 to 4.5 months)."

According to Banoun, public health authorities are aware of this discrepancy, noting that in the HAS Transparency Commission's

report on Beyfortus, Sylvie Chevret, M.D., Ph.D., professor of public health and biostatistics at France's Université Paris Cité, said:

"In these trials, they included children who were essentially said to be in good health, so tomorrow, do you intend to give this drug to all newborns, bearing in mind that the studies did not include newborns?

"They included children who were less than three months old, of course, but up to more than 6 months."

"The FDA and the American Association of Pediatrics jumped the gun in 2023 and were reckless in the approval and recommendation of Beyfortus for mass deployment in babies without carefully considering these issues," McCullough told The Defender.

'Expectant mothers should be prepared to resist' Beyfortus for their babies

Despite these indications and possible safety signals, Banoun said that there has been no reaction so far from public health authorities in France or elsewhere.

"The only reaction to my posts was censorship and a video that was supposed to debunk my claims but actually confirmed them," she said. "Like all critical scientists, I am censored: strict control over social networks, in particular Twitter, where we have been rendered virtually invisible since December 2023, when the European Digital Commissioner threatened Twitter with heavy fines."

"When all debate is censored, all criticism discredited, even

penalized and ostracized, can we still speak of 'science'?" Banoun questioned, tying the censorship she's experienced and the promotion of drugs such as Beyfortus to the concept of biopolitics.

Banoun explained that biopolitics was theorized by French philosopher Michel Foucault "to explain how power is exercised over human populations … on a global level" and "which, in our time, tends to impose health standards on all human populations [and] increasingly relies on vaccination as an alternative to care in infectiology."

"Biopower today is exercised by an alliance of governments and health agencies with big industry," she added.

"Biopolitics [also] concerns the control of populations in fields other than health: digital identity and climate.

For Banoun, financial interests are a key reason for this stance on the part of public health authorities and pharmaceutical companies.

"The market for bronchiolitis prevention will therefore represent several billion dollars for Big Pharma in the years to come. Why such a large market for a disease that is benign in the vast majority of cases? …

"The giants of the pharmaceutical industry are in permanent financial difficulty because of the fines and compensation they have to pay."

"To compensate for these fines, manufacturers have to launch 'blockbusters' — highly profitable products that sell very well," Banoun said, adding that the vaccine liability shield afforded to vaccines by laws such as the National Childhood Vaccine Injury

Act of 1986 may be extended to treatments and drugs other than vaccines.

"It is feared that this exemption from liability will be extended to preventive therapies such as Beyfortus," Banoun said, pointing out that U.S. and European authorities have mixed the classification of Beyfortus, considering it a vaccine in some instances and not in others.

In the U.S., the CDC's Advisory Committee on Immunization Practices recommended adding Beyfortus to the childhood vaccine schedule, providing its manufacturers with a waiver of liability, but also recommended coding it as a drug for insurance purposes and leaving it out of the National Vaccine Injury Compensation Program (NVICP).

In addition to this liability shield, Banoun said that, in France, midwives and nurses reportedly "receive a bonus for each injection — Sanofi pays a sum to each hospital, which is then redistributed to the injectors."

Experts advised parents and physicians to be wary of Beyfortus.

"Physicians and parents should be conservative in deciding on Beyfortus. I do not recommend it for parents who are expecting healthy newborns or babies without severe pulmonary disease," McCullough told The Defender.

Banoun said "Expectant mothers should be prepared to resist," noting the White House's and CDC's efforts to promote Beyfortus and pressure placed on new mothers in French hospitals, where "nursing staff insist on giving it to the mother up to four or five times during her stay in the maternity ward."