Vaccine trial's integrity raises questions about inoculating our kids

By Dzulkifli Abdul Razak - November 9, 2021 @ 12:10am

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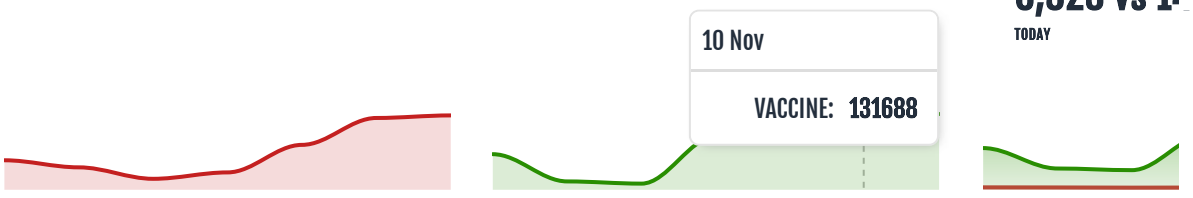
COVID VACCINATION

TOTAL CASES
2,528,817 1.3%
Last 7 days

TOTAL VACCINE
50,946,620 9.1%
Last 7 days

10 Nov
VACCINE: 131688

CASE VS VACCINE
6,323 vs 1
TODAY



ON Aug 16, this column highlighted an editorial in the *British Medical Journal* (BMJ) that was highly critical of the activities of a named vaccine manufacturer in an article, "Profiteering from vaccine inequity: a crime against humanity?"

It raised ethical concerns. On Nov 2, the same journal highlighted another unethical exposition from a whistle-blower in the same manufacturer revealing "poor practices at a contract research company helping to carry out Pfizer's pivotal Covid-19 vaccine trial raise questions about data integrity and regulatory oversight".

Paul D. Thacker reported that "for researchers who were testing Pfizer's vaccine at several sites in Texas during that autumn, speed (of science that company claimed to be operating at) may have come at the cost of data integrity and patient safety".

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told BMJ that the company falsified data, unblinded patients, employed inadequately trained vaccinators, and was slow to follow up on adverse events reported in Pfizer's pivotal phase three trial.

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Staff who conducted quality control checks were overwhelm-ed by the volume of problems they were finding.

After repeatedly notifying Ventavia of these problems, the regional director, Brook Jackson,
emailed a complaint to the United States Food and Drug Administration (FDA).

Jackson provided BMJ with dozens of internal company documents, photographs, audio recordings and emails.

This is despite her repeatedly informing her superiors of poor laboratory management, patient safety concerns and data integrity issues during the two weeks she was employed at Ventavia in September last year.

She was a trained clinical trial auditor who was previously a director of operations and came to Ventavia with more than 15
years' experience in clinical research, coordination and management.

Exasperated that Ventavia was not dealing with the problems, she documented several issues and took photographs with her mobile phone.

One of them, provided to BMJ, reportedly "showed needles discarded in a plastic biohazard bag instead of a sharps container box. Another showed vaccine packaging materials with trial participants' identification numbers written on them left out in the open, potentially unblinding participants".

According to the trial's design, unblinded staff were responsible for preparing and administering the study drug (Pfizer's vaccine or a placebo).

This was to be done to preserve the blinding of trial participants and all other site staff, including the principal investigator.

However, at Ventavia, Jackson told BMJ that drug assignment confirmation printouts were being left in participants' charts, accessible to blinded personnel.

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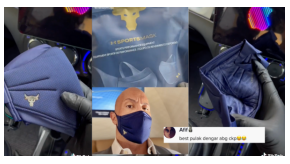

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recruitment and with 1,000 participants already enrolled, quality assurance checklists were updated with instructions for staff to remove drug assignments from charts.

Later that month, allegedly in a meeting, a Ventavia executive can be heard explaining that the company wasn't able to quantify the types and number of errors they were finding when examining the trial paperwork for quality control.

"In my mind, it's something new every day. We know that it's significant," a Ventavia executive said.

Unfortunately, this is just the tip of the iceberg,

Not surprising, Jackson, after warning FDA about unsound practices in Pfizer's clinical trial at Ventavia, was fired as she was deemed "not a good fit," according to her separation letter.

Later, when she reconnected with former Ventavia employees who either left or were fired from the company, most seemed to echo her observations against the manufacturer.

We are often warned against false or unreliable information about vaccines that could bring harm and distort decision-making for the public and professionals.

Even professionals would not have known any better if not for information from credible sources like BMJ and conscientious scientists like Jackson.

This episode raised questions as to how many more of these incidents are occurring in other laboratories worldwide.

What assurances can the public have in contemplating vaccination for children below 12 years old?

The writer, an NST columnist for more than 20 years, is International Islamic University Malaysia rector

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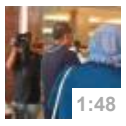

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