

How an untested drugs scandal could lead to better clinical practice

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Cancer researchers and patients from all over the world can learn valuable lessons from a recent Brazilian scientific scandal, according to a new policy paper published in *ecancermedicalscience*.

In Brazil, the distribution by "researchers" to patients of an untested compound called phosphoethanolamine (PHOS) led to a widely publicised scientific debacle.

The dangers of taking unproven compounds as medicines should be obvious - or are they?

"Actually, this question goes much deeper than the patient's right to try any kind of treatment they feel may help them," answers lead author Dr Noam Pondé of the Jules Bordet Institute, Brussels, Belgium. "The danger of unproven drugs has wider societal consequences."

While cancer patients and their advocates may find the process of cancer drug discovery to be opaque or frustrating, the authors of the policy paper argue that the process is an essential part of clinical research.

"I think one of the main messages is that actually, there is no such thing as 'bureaucracy' when we talk about drug development," says author Dr Felipe Ades of Hospital Israelita Albert Einstein, São Paulo, Brazil. "The lab and clinical research phases exist for a very clear and specific purpose, which is to test the real efficacy and safety of a novel drug candidate."

In the case of phosphoethanolamine, a retired Brazilian professor taught a salesman how to make the compound—and the salesman began to sell it to cancer patients. As word of mouth spread, more and more patients began to demand the compound.

The problem? It isn't legal to sell untested compounds as medicines in Brazil - and phosphoethanolamine was untested. Even now, as the scandal continues to unfold, it isn't clear exactly what the compound's effects might be.

"When these important clinical research phases are skipped, for any reason, it put patients into dangerous situations," explains Dr Ades. "The resulting decisions about treatment are not based on clinical and scientific evidence—but on fears, and possibly false hopes."

In the paper, the authors explain the convoluted legal tangle resulting from the fiasco, examine the ethical repercussions, and suggest lessons for the research community to learn.

"I hope that this scandal leads people to understand that miracles cures do not exist for cancer—nor for any other disease," says Dr Pondé, "And that good research methods are as important as having good intentions."

The authors hope that other researchers - as well as scientific reporters and [cancer patients](#)—will be able to learn valuable lessons from the examples they've drawn.

More information: Noam Pondé et al. Phosphoethanolamine and the danger of unproven drugs, *ecancermedicalscience* (2016). [DOI: 10.3332/ecancer.2016.681](https://doi.org/10.3332/ecancer.2016.681)

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