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Editorial

The health products scandal and the problem of perfluorocarbon fluids[☆]



El escándalo de los productos sanitarios y el problema de los perfluorocarbonados líquidos

J.C. Pastor Jimeno

Universidad de Valladolid, Valladolid, Spain

In view of the information being released by the Consortium of Investigation Journalists involving several health products, including some for ophthalmological use, as a member of a team that has been researching these issues for over 3 years, I consider it is my duty to express our opinion and some of our experiences.

Initially, I believe that the style in which some media are presenting said information is not the best. It seems to be an alarmist style containing a number of falsities that emphasizes only the negative aspects. However, many of the issues underlying said scandal include significant percentages of truth. I was particularly disturbed by the fact that said information did not even mention that patients, ophthalmologists and the rest of medical professionals have felt deceived and are on the side of the damaged groups that have no options for taking action.

In the specific case of perfluorocarbon fluids, Spanish ophthalmologists have acted impeccably, officially reporting each suspect case to the Agency of Medicaments and Health Products of Spain (AEMPS in Spanish), who have always reacted without delay. However, it is true that some companies have endeavored to conceal information and put the blame on us. In March 2018, at the Chemistry Congress of North America, a company issued a release stating that this was “a Spanish problem”. And in the recent Congress of EURETINA held in

Vienna, a member of the International ISO Standards Committee also referred to the adverse effects of the Ala Octa as “the Spanish problem” from the very first slide of his presentation.

The fact is that since October 2015 we know that many of the cytotoxicity tests carried out as per the ISO standards were not able to detect toxic batches, and that to date some companies have not modified them. And this is not because they don't know about it because, in addition to presenting the issue in multiple meetings and congresses, we have published reports to this effect in high-level journals. Not all manufacturers have changed said tests because, in their words, they comply with ISO standards which allows them to obtain the CE branding. As we know, the CE labeling can get to the point of endorsing a plastic mesh for carrying oranges as a gynecological product.

An additional serious problem was to conceal or attempt to conceal information about acute toxicity cases in other countries. By way of example, a colleague of a University hospital in the Netherlands said she had several consecutive cases of sterile endophthalmitis with silicone oil. When she reported this to the company, it answered saying it was a local problem (?). A further example is that of a Swiss colleague who, in the question and answers round of the session we held in Vienna, publicly said that he had several suspicious cases which he had reported to the Medicaments Agency which in turn had

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E-mail address: pastor@ioba.med.uva.es

raised the issue with the supplier company who denied the existence of any problem. Subsequently, the Agency carried out an audit of the reporting clinic in order to determine if the problem was local.

I was happy to learn that the European authorities called for the creation of a European Health Products Agency. About time. We have been calling for such an agency over 3 years. However, I am not happy with the pressure I have been under (which could be my imagination) at international meetings aimed at ignoring and hindering our initiatives on this issue. It is not acceptable for a manager of a European (not Spanish) company to say that problems occurred with just a handful of cases that fall within normal risks. Normal risks? If the affected patient was a relative of his, would he have considered it as an affordable risk? It is not acceptable either that the former manager of a company that subsequently entered receivership should say that public health services should cover patient compensations. This person also requested an explanation from me at the EURETINA meeting for having shown in a slide the statements attributed to him in an article published in a large nationwide newspaper of Spain. In said article, the journalist reported that the owner of the company affirmed that as his product was very safe, the toxicity

and blindness cases must have occurred due to improper use of perfluorooctane by Spanish ophthalmologists. I replied that if said statement was untrue, I assume he had filed a complaint against the journalist, to which he did not reply.

In my view, the reaction of the public and even less of companies should not occur after a huge scandal like the one that broke out recently. But since this is the case, let us make the most of it: let us not consent the degradation of Spanish ophthalmology, earned after decades of excellent work, due to the manipulation of some companies. We will continue to cooperate with the Spanish medicaments agency (of which we are officially a cooperating organization since September 2018, as published in the Official Gazette on October 22, 2018) through research to make sure that patients will be safe in our care and that the reputation of our colleagues is not questioned. However, a word of caution: all ophthalmologists must continue to be involved in this task and we must continue to report situations in which we suspect that a poor functional result is not due to our own errors (of which, of course, we are not exempted) or lack of ability. One of the few truths of this unfortunate story is that Spanish ophthalmologists have acted impeccably.