

## OZONE AND THE HUMAN COMMITTEE

Shortly after Dr. A. was named Chairman of the Human Committee for the hospital, she called her first meeting and, in no uncertain terms, warned that she would tolerate no tardiness, no double talk, or any lengthy discussions concerning projects submitted to the Committee. Occasionally, she announced, there would be additional meetings held so that there would be no delays in the authorization of projects and grant proposals. She firmly stated that, as Chief of Oncology, she was not going to stand in the way of delays in the carrying out ideas from the staff. She also made it clear that there would be expedited reviews for special projects (compassionate and emergency). The meetings turned out much as she had promised — efficient, very much to the point, and no nonsense. The members of the Human Committee generally were pleased with the way she handled things.

About six months later a resident of W.M.C. presented a project accompanied by a rather vague proposal, neither a grant nor a pharmaceutical project, but one which he labeled “Personal Interest.” The project consisted in treating the skin of all patients having bedsores with a stream of ozone. The Chairman was enthusiastic, stating that we had almost two dozen such patients and that they did not respond effectively to the antibiotics used.

At this point José presented several questions challenging the project. First, he wanted to know, what was the rationale? Second, what preliminary work had already been done on animals? Third, how was the ozone going to be generated and delivered? And finally, did the resident realize the toxic properties of ozone in a system where the patient could inhale this material?

The resident exploded. Angrily, he argued that this was an idea that deserved a trial, and that this would be the only way for a discovery to be made. José inquired as to how much of the literature the resident was familiar with, especially on the toxicity of ozone gas, and whether he knew how he would administer the material. Had he tried ozone on hairless animals?

The resident’s reply was that you must give new ideas a chance and, he wanted to know, exactly what made José such an expert on the topic. To this José replied that he had published seven papers on ozone toxicity in the lungs of various animals. Then the resident suggested a compromise. Let him have just two patients, he proposed, and if they improved, then the others could be added later. Without allowing José to reply, Dr. A. called for a vote which, except for José, turned out to be unanimous in favor of trying the procedure on two patients.

José immediately demanded a minority report to be incorporated into the minutes, in which he went on record as opposing the use of any human subject at all in this project. He was particularly adamant about this, especially since there had been no precedents of skin lesions ever handled with ozone, nor were there any suitable facilities for flushing ozone onto the skin of a patient. The meeting was finally adjourned with the minutes stating that the project was approved eighteen in favor, one opposed.

About three to four weeks later Dr. A. came angrily searching for José. Why, she demanded to know had he notified the FDA in Washington about this project, demanding its rejection? José assured her that he had never called anyone in Washington nor the FDA concerning this matter, nor had he discussed the project with anybody else. Taken aback, she announced that she would get to the bottom of this. José suggested that she call the FDA herself to inquire what was going on.

A few days later, she again approached José. She had learned that a company which manufactured ozonizers (machines which deliver ozone in a jet stream) had applied for an IND permit to use such a machine in humans. As it turned out later, the resident who had suggested the project had been trying to obtain a grant from this manufacturing company by informing them that he had already gotten permission to test out the idea.

Dr. A. immediately withdrew the project. Ever after that, she gave special weight to José's opinions whenever the Human Committee met and entered into discussions on upcoming projects.