Burzynski Research Institute, Inc. and Burzynski Clinic Summary of Response to the FDA Warning Letters

The FDA's observations listed in the Warning Letters deal with technicalities of evaluation of responses, consent forms, financial disclosure, overdosing of medications by the patients, and differences in case reports in phase II trials with antineoplastons. All responses were determined by outside radiologists based on current criteria, but FDA inspection did not include a review of the films and expert radiology review. The consent forms were previously reviewed by the FDA and none of the sub-investigators received any compensation for participation in the trials; therefore, there was nothing to disclose. The treatment was self-administered and occasionally the patient took an increased dosage that caused him sleepiness. There were no discrepancies in the case reports. The first report included a complete description of the patient's condition, but the second form was required to include only abnormal findings.

The FDA inspectors had access to 2 ½ million pages of documents covering 19 years of phase II trials with antineoplastons, but what they found were minor technicalities. It is surprising that they did not pay attention to 77 cases of eligible trial patients who survived over five years instead of dying within a year from incurable brain tumors. Knowing that approximately 100,000 Americans suffer from such brain tumors, and knowing that the treatment with antineoplastons can theoretically save approximately 20% of them, this would translate to 20,000 human lives saved every year. Somehow, this important information for American people completely escaped the attention of the FDA agents.