April 26, 1995

To: Philip Lee, M.D. and Harold Varmus, M.D.
From: Alternative Medicine Program Advisory Council members
Re: The Federal Government and Dr. Burzynski

On Friday, March 24, 1995, Stanislaw R. Burzynski, M.D., Ph.D. appeared with three of his patients on the *CBS This Morning* show. He spoke about his antineoplaston (non-toxic peptide) treatment for cancer and the patients presented their stories. Two had had non-Hodgkin's lymphoma and one had had brain cancer. All claimed to be in complete, long-term remission and spoke forcefully and eloquently about their experiences. Dr. Burzynski mentioned several times that he would treat those patients who enrolled in the FDA-approved clinical trials free of charge. There were over 2,000 inquiries at the Burzynski Research Institute (BRI) on that and on subsequent days.

At around 2 PM, Dr. and Mrs. Burzynski got on a plane from New York to Houston. Fifteen minutes later, the FDA obtained a Search and Seizure Warrant from U.S. Magistrate Frances H. Stacy and just past 5 PM, seven agents of the FDA and a postal inspector entered BRI in Houston. All clinic employees were escorted into the conference room, including a nurse who had been treating a patient. They then began their search and seizure, concentrating on the records of 17 patients on a list. Nine names corresponded to active patients. The FDA also took a list of the names, addresses, and phone numbers of *all* Burzynski patients.

Arriving home, Dr. Burzynski was alerted to the raid and arrived at the clinic. He finally convinced the FDA agents to allow him to make copies of the files they were taking, because otherwise he could not treat the active patients. At around 8 PM, Richard Jaffe, Dr. Burzynski's lawyer, arrived at the clinic. The FDA search was finished around 11:30 PM. Dr. Burzynski, as custodian of the Institute's records, and two other employees were given subpoenas to testify before a Grand Jury and bring additional documents on April 17, 1995. On various occasions since then, Dr. Burzynski's clinic has been under surveillance, with agents taking down license plate numbers of those entering the facility.

The main legal issue seems to be the purported shipment of medicine across the state line. We say "seems" since the charges have been sealed, and FDA representatives refuse to comment or meet with members of our advisory council. We have no independent knowledge of the legal issues. But we have been told that BRI has a very strong policy against interstate shipment. Employees are repeatedly warned never to send medicine outside the State of Texas. If it is found that they are involved in such an act their employment is immediately terminated.

The FDA raid came as a particular shock to us because the Office of Alternative Medicine has entered into a good collaborative relationship with the FDA to facilitate the examination of a number of alternative treatments, including that of Dr. Burzynski. The FDA has facilitated several Investigative New Drug (IND) applications for antineoplastons. Just days before the raid, Freddie Ann Hoffman, M.D. of FDA attended an OAM meeting at which Burzynski's relationship with both the OAM and FDA was favorably discussed. Dr. Hoffman assures us she had no prior warning of any problem with Dr. Burzynski on FDA's end. If there had been any concerns voiced to either OAM or the Burzynski Research Institute, these might have been corrected without resorting to such drastic measures.

The FDA raid harks back to the type of relationship that existed between the alternative community and the FDA prior to the establishment of the OAM. We feel this latest action was taken without a thorough review of its likely consequences. While we support a legitimate drug regulatory role for FDA, this action only feeds sentiments in the public that could undermine the proper regulation of the pharmaceutical industry. It also has a chilling effect on the OAM's ability to recruit alternative clinicians to participate in rigorous scientific review of their methods. Since your office, Dr. Lee, has responsibility for the entire Public Health Service, including the FDA, we urge you to fully investigate this matter. We stand ready to advise you in this review.

Dr. Varmus, we would also like to call your and Dr. Lee's attention to another matter that relates to the National Cancer Institute (NCI). We feel this may also jeopardize the fair evaluation of antineoplastons.

Without Dr. Burzynski's knowledge or permission, Memorial Sloan-Kettering Cancer Center recently amended the protocol for testing antineoplastons in adult patients with advanced brain tumors. Previously, by agreement with the developer, only patients whose brain tumors were no bigger than 5 centimeters (cm) in diameter were accepted into the antineoplaston program at MSKCC. Now, MSKCC, NCI, and FDA have agreed among themselves to accept patients with any tumors, including those larger than 5 cm, as well as with multiple tumors, distant metastases, and lower Karnofsky (performance) scores. If the treatment fails, then this will probably be chalked up against antineoplastons and non-toxic treatments in general. Yet at the dosage levels and with the combinations of drugs stipulated in the original protocol, in Burzynski's view, the treatment almost certainly will fail. All parties are aware of this fact.

The rationale given for this change is that with wider criteria more patients can be recruited into the trials. This would be a desirable change. However, according to Dr. Burzynski, these particular antineoplastons at these dose levels were designed to treat less advanced patients with small to medium-sized tumors. Since most of these advanced patients will almost certainly die on the treatment, it is difficult to see how this will yield any meaningful (much less positive) results.

Dr. Burzynski, as the discoverer, has had over 20 years experience with these substances. We feel he should have been involved in any changes of the protocol. We also feel that, if only because OAM paid for this trial, either the OAM's Acting Director, Alan Trachtenberg, M.D. or its Director Designate, Wayne Jonas, M.D., should have been involved in this decision. Neither was consulted.

OAM was formed to bring to an end an unfortunate era in which opinions on alternative methods were sharply polarized, and in which it was difficult to obtain fair, scientific evaluations of such treatments. In our opinion, the OAM and the Alternative Medicine Program Advisory Council (AMPAC) have been and remain committed to insuring that promising alternative therapies receive this kind of thorough and unbiased evaluation. We know that you support the work of the OAM and concur with this approach. Accordingly, we, the undersigned members of AMPAC, would like to work with you and your office to ensure such a fair and thorough evaluation of antineoplastons.

We understand that you have asked Dr. Michael Bishop to undertake a comprehensive review of the National Cancer Institute. We would like Dr.

Bishop to take a fresh look at the way that NCI has been evaluating alternative therapies and its handling of antineoplastons in particular. We think it would be extremely helpful if he would meet with representatives of the OAM and its advisory council.

Dr. Wayne Jonas has expressed his interest in working cooperatively with the NCI in establishing a fair and objective process for monitoring and evaluating clinical trials of unconventional therapies and has suggested that this meeting might be used to begin development of such a process.

Thank you both very much for your consideration of the above matters. We look forward to hearing from you.

Sincerely,

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