June 30, 2014

The Honorable Margaret A. Hamburg, MD
Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Re: Dr. Stanislaw Burzynski and antineoplaston clinical trials

Dear Commissioner Hamburg,

We write to you again on behalf of the medical professionals, policy experts, and patient advocates affiliated with the Center for Inquiry, a non-profit advocacy and educational organization whose mission includes examining the scientific efficacy of alternative medicines and the scientific integrity of public policy. Our concern remains the ongoing matter of Houston, Texas researcher Dr. Stanislaw Burzynski, MD, PhD, and his experimental antineoplaston (ANP) cancer treatment.

It is our understanding that the FDA has decided to allow the restoration of his status as a researcher and the resumption of Investigational New Drug clinical trials overseen by an Institutional Review Board (IRB) that is beholden to him. Given the behavior of Dr. Burzynski and the Burzynski Research Institute (BRI) over the course of more than three decades of failed research and trials, and in the face of a complete lack of scientific evidence demonstrating the efficacy of their expensive and dangerous antineoplaston treatment, we find the FDA's decision perplexing and profoundly disturbing.

As our April 16, 2014 letter to you described[1]—and as amply documented by FDA inspectors themselves over the course of their decades-long review of the work of the Burzynski Research Institute—the BRI, its principal, and its staff have proven themselves incapable of following their own protocols, protecting patient rights, maintaining independent institutional review, or even maintaining accurate patient records. Significantly, not only has Dr. Burzynski failed to show for nearly forty years that his antineoplaston treatment is effective, but the clinical trials he has been permitted to conduct for seventeen years have been dismal failures, with the only apparent predictable result the needless endangerment of patients. After seventeen years of clinical trials testing treatments for diseases that develop very rapidly, any competent researcher should also be able to demonstrate results that justify their efforts, especially for care that commands such exorbitant fees as Dr. Burzynski's does. Yet even after such a length of

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[1] Center for Inquiry. "Coalition of Experts to FDA: Protect Cancer Patients from Burzynski's False Cures." April 16, 2014, accessed June 26, 2014. http://www.centerforinquiry.net/opp/news/coalition_of_experts_to_fda_protect_cancer_patients_from_burzynskis_false_c/

time, proof that Dr. Burzynski's experimental treatment actually works remains tellingly and damningly absent. As such, it is our position that any patients who have ever paid—or are currently paying—to be subjected to the scientifically unfounded, medically dangerous Burzynski protocols have been exploited, and continue to be exploited, at their most desperate and vulnerable moments.

We are frankly stunned to hear that the clinical hold against Dr. Burzynski has been lifted, and we find ourselves even more discouraged that the FDA appears willing to accept Burzynski's own IRB as overseer for his clinical trials. This situation presents an unethical conflict of interest which defies the very purpose of an institutional review board: *independent* oversight and review in the name of scientific rigor and patient safety. FDA approval of trial oversight by a party intricately related to Dr. Burzynski and the BRI maintains the corrosive ethical environment that has marred the Burzynski Research Institute and its IRB for years—one of their critics' main charges. Given Dr. Burzynski's associates' clear inability to run a clinical trial to the satisfaction of FDA standards, and their failure to publish to the satisfaction of their peers over the course of decades, we respectfully request an explanation as to how and why the Burzynski Research Institute's continued operation can be tolerated by the FDA.

One can certainly understand the desire of the terminally ill to attempt experimental treatments, even dangerous experimental treatments, to try to save or prolong their lives. However, one role of the FDA is precisely to protect vulnerable patients from exploitation. The lamentable record of the Burzynski Research Institute amply demonstrates that it has served as a means of extracting significant amounts of money from those patients, their families, and well-meaning supporters at that time of their greatest need.

Even under the prior restrictions placed upon Dr. Burzynski by the FDA—by which only other, independent physicians were able to treat new patients using Dr. Burzynski's experimental antineoplastons—patients have reported suffering the unethical profiteering that constitutes the BRI business model. Under this model, although Dr. Burzynski has proudly and loudly claimed that he has offered his antineoplastons to patients for free, he has still charged them tens of thousands of dollars, ostensibly for the general monthly costs of running the trial.[2] This has come to the shock and dismay of some of the very independent physicians who have volunteered to administer the antineoplastons to patients.

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[2] Morrill, Dylan. "Controversial cancer treatment begins today." *The Forster Daily Democrat,* June 24, 2014*,* accessed June 26, 2014. http://bit.ly/1qBFMcz

According to a June 22, 2014 report in the Forster Daily Democrat:

> "[A]fter learning last month that [patient McKenzie] Lowe's treatment is going to cost tens of thousands of dollars, [Lowe's sponsoring physician] Bennet is questioning his sponsorship of Lowe and the motivation of the Houston, Texas doctor [Burzynski] who is supposed to provide the controversial 'antineoplastons therapy' treatment."[3]

Then on June 23, again from the same independent doctor volunteering to administer the treatment:

> "Bennett says a representative of the Burzynski Clinic called him on that date seeking payment for the first month of McKenzie's therapy. Prior to that, Bennett, who is donating his services, thought Burzynski was doing the same.
>
> "Instead, said Bennett, 'I'm supposed to be the bag man for all of this. They want me to collect the 30 grand for the family and send it to Burzynski.'"[4]

On June 24, with the family facing a first-month bill from Burzynski of $28,000, with $16,000 to be charged for each following month of treatment, Dr. Bennett summed his thoughts:

> "It meets all the criteria for a bait and switch operation."[5]

We struggle to see why the FDA continues to enable this deceptive, antiscientific, and unethical medical adventurism, even for patients who are terminally ill. Not only does it enable the active harming and impoverishment of vulnerable patients and their families, but tolerating the BRI's behavior sabotages other, more promising trials into rare and deadly diseases by depriving those trials of patients. For this reason, and in the interest of public accountability in general, we are also forwarding this letter to Liz Szabo, the USA Today journalist who compiled last year's expose about Burzynski[6], and who first reported

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[3] Morrill, Dylan. "Teen's Controversial Cancer Treatments Raise Concerns." *The Forster Daily Democrat,* June 22, 2014, accessed June 26, 2014. http://bit.ly/1qPSRRN

[4] Morrill, Dylan. "Dr. feels misled in cancer treatment costs." *The Forster Daily Democrat,* June 23, 2014, accessed June 26, 2014. http://bit.ly/1lLUdeC

[5] Morrill, Dylan. "Controversial cancer treatment begins today." *The Forster Daily Democrat*, June 24, 2014, accessed June 26, 2014. http://bit.ly/1qBFMcz

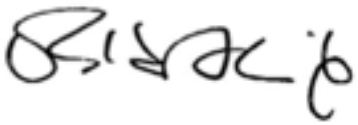
[6] Szabo, Liz. "Doctor accused of selling false hope to families." *USA Today*, January 14, 2014, accessed June 26, 2014. http://www.usatoday.com/story/news/nation/2013/11/15/stanislaw-burzynski-cancer-controversy/2994561/

on the lifting of the FDA's clinical hold last week.[7]

We also respectfully request an account of how Dr. Burzynski, a researcher without a single completed phase II study published in a reputable, peer-reviewed medical journal, has managed to secure phase III clinical trials. Such an exception cannot be reconciled with the FDA's established procedures, nor its general obligation to protect patient safety.

We thank you in advance for your prompt attention to this matter and look forward to a response. We once again encourage you, in the interest of public safety, to revoke Dr. Burzynski's status as a researcher, shutter his compromised IRB, and end his antineoplaston clinical trials permanently.

Respectfully,



Michael De Dora, MA
Director, Office of Public Policy
Center for Inquiry

Ronald A. Lindsay, JD, PhD
President & CEO
Center for Inquiry

CC: Patricia Keegan, MD, Director, Division of Oncology Products 2, Office of Hematology and Oncology Products, Center for Drug Evaluation and Research

Jerry Menikoff, MD, JD, Director, HHS Office of Human Research Protections

Liz Szabo, *USA Today*

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[7] Szabo, Liz. "FDA gives controversial doctor green light to restart work." *USA Today*, June 25, 2014, accessed June 26, 2014. http://www.usatoday.com/story/news/nation/2014/06/25/burzynski-trial-reopens/11353085/