MAJOR EVENTS IN THE DR BURZYNSKI/ANTINEOPLASTONS STORY

- In 1977, Dr Burzynski began the process to have antineoplastons approved by the US Food and Drug Administration (FDA) for use as a human cancer drug
- He continued to administer the unlicensed 'experimental', antineoplastons – upon which, crucially, Dr Burzynski owns the patents – to patients from across the USA at his Texas clinic, after ensuring that it was legal do so in the state. Interstate trade in antineoplastons was, however, illegal
- After requesting and receiving details of 40 cases successfully treated by Dr Burzynski, the Texas Medical Board (TMB) threatened to revoke his license under a non-existent law and harassed him for 5 years
- Finally, in 1993, the TMB's case against Dr Burzynski went to trial – and was dismissed as groundless by an administrative law judge, Judge E Corbitt
- Undeterred, the TMB found reasons to ignore the judge's findings and took Dr Burzynksi's case eventually to the US Supreme Court, which issued a probation order that Dr Burzynski served. It later emerged that the TMB's vendetta against Dr Burzynski was prompted by FDA pressure
- In all, Dr Burzysnki underwent four Grand Jury hearings organised by the FDA, none of which resulted in an indictment
- One week after a Congressional Oversight and Investigations Subcommittee hearing at which many of his patients testified on his behalf, Dr Burzynski was indicted by the FDA on multiple charges – facing 290 years in prison and a fine of $18,500,000
- With the jury hung, the judge acquitted Dr Burzynski of nearly half of the charges against him, finding that the FDA had provided insufficient evidence
- So the FDA tried yet again, but suddenly dropped all but one charge in May 1997, upon which he was subsequently acquitted
- Following public and Congressional pressure, the FDA agreed later in 1996 to accept antineoplastons into a series of up to 72 Phase II clinical trials: a bizarre situation where the FDA was prosecuting a scientist for using a drug upon which the scientist was performing FDA-approved clinical trials!
- The NCI altered the protocols used in these trials against Dr Burzynski's clinical recommendations – based on 20 years' experience – in ways that guaranteed suboptimal results. For example, the NCI used a low dose of antineoplaston in patients with advanced cancer
- Rather than follow the protocol Dr Burzynski recommended, the NCI terminated the trial early, preventing conclusions from being drawn. Yet, four years later, the NCI published the results in a peer-reviewed journal, thereby placing unfairly negative information into the public domain. Dr Burzynski's attempt to bring the truth to light failed
- Many other antineoplaston trials are still ongoing

- Dr Burzynski is providing funding for an FDA-approved, Phase III clinical trial – the first independent, patent-holding researcher ever to do so
- On 4th October 1991, the NCI visited Dr Burzynski's clinic – and filed a patent for antineoplastons AS2-1 seventeen days later, a substance for which Dr Burzynski already owned the patent. By the end of 5th June 1995, the US government had filed eleven antineoplaston patents, all of which were approved by the US Patent Office. At the time, of course, Dr Burzynski was fighting to stay out of jail on FDA charges
- A colleague of Dr Burzynski at the time, Dvorit Samid, and Élan Pharmaceuticals tried to replicate his results using phenylacetate, an unpatented molecule present in one antineoplaston mixture. As they found out, rather expensively, phenlyacetate has has little clinical efficacy on its own
- In November 2011, the TMB tried once more to revoke Dr Burzynski's medical license, this time for off-label drug use; and once again, it failed after judges dismissed most of the charges