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REPORT



The FDA's Vendetta Against Dr. Burzynski

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Stanislaw R. Burzynski is an MD with a Ph.D. in biochemistry. In 1967, while studying blood as a graduate student, he found certain peptides that had never been described before.

Comparing the blood of patients with different diseases, Dr. Burzynski found that over 98% of cancer patients were deficient in the peptides he had found-often with blood levels of only 2% of those of healthy individuals. This led him to suspect that these compounds-or a lack thereof-were implicated in the development of neoplastic (cancerous) disease.

Most cancer experts believe we all develop cancer cells hundreds if not millions of times in our lifetimes. Given the trillions of developing cells, the millions of errors that can occur in the differentiation (maturing) process of each cell, and our constant exposure to carcinogenic substances (smoke, car fumes, radiation, etc.), the laws of probability dictate that mis-developing cells must occur frequently in the life of each individual. It stands to reason that a healthy body has a corrective system to "reprogram" newly-developed cancer cells into normal differentiation pathways before the cancer can take hold.

Dr. Burzynski postulated that healthy organisms have just such a corrective mechanism, which he termed the "Biochemical Defense System." He called the substances produced by this system "antineoplastons." Their purpose is to "reprogram" cancer cells to die like normal cells. Healthy cells are not affected.

Dr. Burzynski continued his research at Baylor University until 1977, when he felt he was ready to begin treating advanced cancer patients with the peptides he had discovered. After getting a written opinion from his lawyer that doing so would not violate any state or federal laws as long as he treated patients only in Texas, Dr. Burzynski began to give antineoplastons to patients with hopeless cancers-often with dramatic results.

The FDA Seeks An Injunction

In 1983 however, the FDA went to court for an injunction to stop Dr. Burzynski from manufacturing or using antineoplastons in his practice. U.S. District Court Judge Gabrielle McDonald turned them down. In an 18-page decision, Judge McDonald made it clear that Dr. Burzynski could continue to "manufacture, package, sell, and distribute antineoplastons, so long as it occurs wholly intrastate."

Ignoring Judge McDonald's decision, the FDA tried to stop Dr. Burzynski by writing dozens of letters to Senators, Congressmen, insurance companies and pharmaceutical firms. These letters contained lies and distortions so outrageous that on October 23, 1985 Judge McDonald issued a Cease and Desist order, commanding the FDA to stop issuing false and misleading information about Dr. Burzynski.

A Series Of Raids And Grand Jury Investigations

In 1985, FDA agents and armed Federal Marshalls raided Dr. Burzynski's clinic and seized all his patient records-200,000 documents in all. In order to continue treating patients with advanced cancer, Dr. Burzynski had to install a copier-at his expense-at FDA headquarters and hire someone to shuttle back and forth, making copies of his records and bringing them back to the clinic. Dr. Burzynski had to make appointments with the FDA to make copies of his own documents.

Later in 1985, Federal prosecutors representing the FDA presented everything they seized in the raid-plus another 100,000 documents subpoenaed shortly after the raid-to a Federal Grand Jury. Their investigation of Dr. Burzynski lasted nine months, but prosecutors couldn't convince the Grand Jury that there was probable cause to believe a crime had been committed. No indictment was returned.

In 1990, the U.S. Attorney's office in Houston, representing the FDA, convened another grand jury to investigate Dr. Burzynski, again for alleged violations of Judge McDonald's order. To the FDA's dismay, this Grand Jury also refused to indict Dr. Burzynski.

More Raids And Grand Juries

In 1993, the FDA again raided the Burzynski Research Institute because of alleged bacterial contamination of antineoplastons, but tests proved conclusively that there was no contamination.

In 1994, U.S. Attorneys-again representing the FDA-convened a third Grand Jury to investigate Dr. Burzynski. And for the third time, a skeptical Grand Jury refused to return an indictment. The main casualty this time was the Assistant U.S. Attorney on the case, who was removed for prosecutorial misconduct involving abusive and improper use of subpoenas.

The latest chapter in the FDA's twelve-year campaign to stop Dr. Burzynski from treating patients with antineoplastons kicked off on March 24, 1995 with another raid on the clinic. Seven federal agents herded employees into a room and kept them there until they filled out forms with personal information. They then spent seven hours rifling through file cabinets and drawers, leaving with Boxes of patient records and other documents.

Shortly thereafter the FDA began serving clinic employees with subpoenas commanding them to testify before a Federal Grand Jury investigating Dr. Burzynski. To date, federal prosecutors representing the FDA have subpoenaed nine employees including Dr. Burzynski. In addition, they have ordered him to turn over tens of thousands of pages of documents, including more patient records and diagnostic films.

An Arbitrary Fishing Expedition

The law prohibits Grand Juries from "arbitrary fishing expeditions". Yet that is exactly what federal prosecutors are engaged in. Besides patient records-many of which have already been presented four times to various government investigators-prosecutors have subpoenaed "any and all agreements, draft agreements, proposals, correspondence, notes, memos, tape recordings, notes of conversations, telephone messages, reports, raw data, studies or other items to, from, or with any foreign or domestic pharmaceutical company or university, including contact person's name, title and phone number."

While this information is of no use in investigating criminal activity, it gives the FDA the opportunity to write letters to everyone they uncover, letting them know that Dr. Burzynski is the target of a federal investigation and to issue subpoenas to some of these people. This is more than just speculation. It is the exact behavior that sparked a 1985 "Cease and Desist" order against the FDA by US District Court Judge Gabrielle McDonald.

And so, on June 15 1995, prosecutor Amy LeCocq subpoenaed a huge Dutch pharmaceutical conglomerate-which has conducted negotiations with Dr. Burzynski-for all correspondence, memos, documents or other records it had regarding Dr. Burzynski or anyone associated with him. The obvious purpose of this subpoena was to frighten the company-which does a large business in the U.S.-into having no further contact with Dr. Burzynski.

Prosecutors have also subpoenaed all patient billing records, again with no time limitation whatever. Dr. Burzynski has been treating patients since 1977. They have subpoenaed his accountants for every conceivable document an accountant can possess (again with no limitation on time), a classic fishing expedition. Prosecutors have even subpoenaed the names and addresses of every person who has ever received a brochure from Dr. Burzynski! As if that weren't enough, the subpoena went on to demand "Any other lists of persons", an absurdly general and burdensome request.

FDA Harassment, Illegal Actions And Terrorism

Besides throwing the entire clinic into chaos, wasting thousands of hours of employee time, and terrifying advanced cancer patients who don't know whether they will be able to continue getting the only medicine that has been able to help them, the grand jury's actions have severely threatened Dr. Burzynski's ability to practice medicine. Without patients' previous MRIs and CAT scans, Dr. Burzynski has nothing to which he can compare new scans, and no way of knowing if patients' tumors are growing or shrinking.

Moreover, the FDA has been careful to seize films and medical records of Dr. Burzynski's most successful cases, crippling his ability to defend himself by confiscating his single most valuable asset-proof of the anti-cancer activity of antineoplastons.

In the current case there has been illegal use of subpoenas as well. Dr. Ralph Moss, an award-winning journalist and author of books about cancer, was subpoenaed and ordered to produce every document in his possession-electronic, magnetic, printed or otherwise-relating to Dr. Burzynski. Dr. Moss has written favorably about Dr. Burzynski in the past.

Unfortunately for Amy Lecocq, the prosecutor in charge of this case, her subpoena of Dr. Moss violated at least six federal laws governing subpoenas of journalists. Such violations carry a penalty of administrative reprimand or other disciplinary action. When Dr. Moss pointed this out to Lecocq and gave her the opportunity to withdraw the subpoena, she did so with alacrity.

It's been said that a prosecutor can get a Grand Jury to indict virtually anyone. But despite the avalanche of documents supplied by the government to four Grand Juries, it has yet to convince any of them of probable cause to believe Dr. Burzynski has committed a crime. And so, unable to stop him legally, the FDA seems determined to harass him to death.

The NCI Report on Dr. Burzynski

The FDA's actions are all the more outrageous because their own oncology division has granted Dr. Burzynski permission to conduct Phase II clinical trials! In addition the National Cancer Institute (NCI)-following a visit by seven NCI experts to Dr. Burzynski's Houston clinic for a review of patient records-confirmed several remissions in patients with "hopeless" brain tumors after treatment with antineoplastons. Their report states that "The site visit team documented anti-cancer activity in this best-case series and determined that Phase II trials are warranted to determine the response rate."

In other words, the question is no longer "Do antineoplastons work?"; it is: "How consistently do they work?"

And yet, despite the NCI report, despite the fact that the FDA's own scientists wish to see antineoplastons tested, the FDA's "enforcers" remain obsessed with shutting Dr. Burzynski down.

How long will this continue? Until your outrage puts a stop to it.

You can start by writing letters, phoning, and faxing your Senators and representatives in the House. To obtain, the phone numbers of your representatives, call the U.S. Congressional switchboard number:

1-202-224-3121

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