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# The Criminalization of Innovation: FDA Misdirection in the Najarian and Burzynski Cases

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1

**Introduction**

John Najarian, transplant surgeon. He is a man whose intelligence, genius, and skill in the operating room have allowed him to pioneer an entire field of medicine. Over the past three decades he has performed countless organ transplants, first at the University of San Francisco and most recently as chief of surgery at the University of Minnesota. In doing so he has almost single-handedly developed the practice of organ transplantation into what could be considered a routine procedure. His collegues in academia revere him: "a giant of $20^{th}$ century medicine," in the words of the University of Pennsylvania's Arthur Caplan.[1] His patients worship him: "I'd go to the ends of the Earth for him," says Charles Fiske of Bridgewater, Massachusetts, the father of Jamie Fisk, whose 11-month old kidney Najarian successfully replaced in 1982.[2] There is no question that this 69-year-old son of Armenian immigrants who passed up a professional football career to practice medicine is a model of the American success story.

Stanislaw R. Burzynski, cancer physician. His development and prescription of a mysterious new cancer drug provided treatment thousands of patients since the opening of his Texas clinic in 1977. The Polish-born physician, who grew up under Nazi and then Soviet rule, has been a source of comfort and a doctor of last resort for many long-time cancer victims "poisoned and burned" by years

[1] J. Madeleine Nash, *Once a Hero: Surgeon John Najarian has saved hundreds of lives. Now he's fighting to save his reputation*," TIME MAGAZINE, May 11, 1995.

[2] *Id.*

of unsuccessful chemotherapy and radiation.[3] In recent years 'Dr. B,' as his patients fondly call him, has evolved into a national folk hero in the populist struggle for access to alternative medical care has even prompted a series of congressional hearings on the ethics and efficacy of such treatments.

Najarian and Burzynski seem the perfect examples of the amazing potential of the American medical establishment. Their visionary work in their respective fields should be celebrated as monumental contributions to society. Rather than being lauded by the nation, though, both men have watched their careers and reputations come hurtling to a disastrous end as they faced criminal charges of fraud, embezzlement, and multiple violations of Food and Drug Administration (FDA) laws which threatened to send them each to prison for the rest of their lives. The FDA charges centered around alleged improprieties involving the prescription of their revolutionary new drugs: Najarian's antilymphocyte globulin (ALG), a "potent cocktail of antibodies" capable of preventing the rejection of transplanted organs,[4] and Burzynski's antineoplastons, the mysterious cancer medication made from compounds found in human urine.[5] In both cases the FDA contended that the men conspired to prescribe and sell the drugs in the absence of agency approval, with each reaping millions of dollars in the process. Both men claim that the FDA is merely extending its claws at the urging of the big-money pharmaceutical interests that they claim control the agency, and that the FDA is "piling on" with additional criminal charges in order to buttress

[3] Jesse Katz, *Cancer 'Pioneer' on Trial After Bucking the System*, Los Angeles Times, Jan. 12, 1997, A16.

[4] Nash, *supra*, note 1.

[5] *United States v. Burzynski*, Indictment, No. H-95-290, p. 2.

their cases.

In the *Najarian* case, the court seemed to agree with these contentions as the surgeon was acquitted on all FDA-related charges last January while a jury found him not-guilty on the other counts a month later. The successful trial outcome was achieved at no small cost, however, as Najarian was abandoned by the University of Minnesota, lost his job, and watched his ALG program get closed down indefinitely. The outcome of Burzynski's case will be determined shortly, as the trial opened two weeks ago in U.S. District Court in Houston. Whatever the outcome, Burzynski, like Najarian, will have difficulty moving beyond the specter of a federal criminal investigation and removing the permanent scars on his reputation. All as penetence for the crime, as the two doctors would claim, of simply doing their jobs.

In cases like these, is the Food and Drug Administration performing its statutory mission to vigorously enforce the law in the public interest? Or, by attacking the use of these "new drugs" and bringing criminal charges against the men prescribing them, is the agency "playing God" by denying, through stringent application of bureaucratic pressure, hopeful patients of the treatments they believe they are entitled to? This paper will analyze the *Najarian* and *Burzynski* cases in depth, with an eye trained on this larger issue. What *is* the true mission of the FDA, and is the agency charting the wrong course to that goal by its use of criminal prosecutions in the new drug arena?

## FDA Statutory Authority to Bring Criminal Actions

The FDA is an agency under the direction of the United States Department of Health and Human Services (HHS). The agency has the statutory mandate to regulate and monitor food and drug aspects of interstate and foreign commerce.[6] The Federal Food Drug and Cosmetic Act (FDCA) allows the FDA to criminalize nearly any one of the "Prohibited Acts" proscribed in 21 U.S.C. §331, including, most relevant to new drug process prosecutions, "...(d) the introduction into interstate commerce of any article in violation of section 344 or 355 of this title. (e) [T]he failure to establish or maintain any record or make any report, required under [relevant provisions of the FDCA]."[7] In other words, the statute gives the agency tremendous latitude in imposing criminal penalties if it so desires. Such a charge becomes a felony if the violation constitutes a second conviction or is found to be committed "with the intent to defraud or mislead."[8] Another provision, 18 U.S.C. §3571, establishes limits of $250,000 for felony charges in such cases and permits up to three years of imprisonment for each count.[9] The final decision on whether to impose criminal charges on an alleged violation of the FDCA rests with the Commissioner of the FDA, the Secretary of HHS, and the Department of Justice. In the end, all decisions are purely within the discretion of the agency.[10]

The FDCA requires that drug companies or physicians apply for an exemption from the FDCA's premarketing approval requirements in order to prescribe in-

[6] 21 U.S.C. §321(d).
[7] 21 U.S.C. §331.
[8] 21 U.S.C. §333.
[9] 18 U.S.C. §3571 serves as an overriding provision for the FDCA fines, yet preserves the incarceration provisions from 21 U.S.C. §333.
[10] Jonathan S. Kahan, *Criminal Liability Under the Federal Food, Drug, and Cosmetic Act—the Large Corporation Perspective*, Food Drug Cosmetic L.J. 314, 316 (1981).

vestigational new drugs (IND). The IND process contains carefully worded requirements involving the maintenance of data regarding the safety and efficacy of the experimental drug.[11] The *Najarian* and *Burzynski* cases are examples of prosecutions involving alleged violations of the IND process requirements.

***United States v. John S. Najarian***

A Brief History of Minnesota-ALG

In the late 1960's, John Najarian first developed ALG at the University of Minnesota. The drug was created from the serum of horses which had been injected with human lymphocytes.[12] In 1970, he and his collegue, Richard Condie submitted an IND application and obtained approval to conduct studies on the drug's safety and efficacy as an anti-rejection medication for organ transplants. They did not, however, receive permission from the FDA to produce the drug at a profit. This became the major issue which would come back to haunt the program.[13] Over the course of more than a decade, Najarian was barraged by more and more of his collegues in the transplant community who heard about the drug's success, and ALG gradually became the norm at nearly every transplant center in the world.[14] "The one-year survival rate for kidney grafts had been about 40 percent," said Dr. David Sutherland, one of Najarian's fellow surgeons at the University of Minnesota. "With ALG, it rose to about 80%."[15]

[11] *See* 21 C.F.R. §§312.64, 312.68.

[12] John W. Lundquist, *United States v. Najarian: A Postmortem on Regulatory Misdirection*, 131 Archives of Surgery 911, Sep. 1996.

[13] Gordon Slovut, *With Trial Over, What Happens to ALG?*, Minneapolis Star-Tribune, Feb. 26, 1996.

[14] Lundquist, *supra*, note 12, at 911.

[15] Slovut, *supra*, note 13.

Due to the increase in demand for the drug, Najarian attempted to find a private drug company to take over production. He was rebuffed, however, because the companies saw the transplant patient market as too narrow. After a brief attempt at production with a small Minnesota-based firm, ALG returned to the University of Minnesota, which decided to build a new $15 million facility for the drug program.[16] By the late 1980's the University was producing more than 40,000 g of the drug for distribution to more than 100 treatment centers around the globe.[17] A 1989 letter from the FDA to the University formally allowed the ALG program to continue to do what it claims it had been doing for years: sell the drug at a price sufficient to cover its costs, but asserting that no profit on the sale would be authorized or permitted.[18] Between 1972 and 1990, the University of Minnesota recovered approximately $79 million in cost recovery sales.[19]

### Criminal Charges Bring Minnesota-ALG to a Crashing Halt

ALG's amazing ride to the top of the medical world received a startling blow in April 1995 when criminal charges were filed in United States District Court in St. Paul, Minnesota. Najarian was charged with a conspiracy to violate the FDCA, including allegations that he failed to report adverse reactions to ALG, that he failed to receive informed consent from patients, and that the $79 million recovered by the University violated the cost recovery authorization given

[16] *Id.*
[17] Lundquist, *supra*, note 12, at 911.
[18] *United States v. Najarian*, Superseding Indictment, No. 3-95-45.
[19] Lundquist, *supra*, note 12 at 911.

by the FDA. In addition to the FDA-related counts, Najarian was also accused of tax fraud, mail fraud, embezzlement, and stealing.[20]

The case went to trial on January 16, 1996. The attorneys for Najarian hoped to paint a picture of FDA acquiescence over a period of more than 20 years, suggesting to those involved with the ALG program that the situation was proceeding in a legitimate fashion. They argued that lapses in oversight, inconsistency among the numerous FDA investigators who oversaw the program[21] and the widespread use of ALG in general rendered the government's case invalid. The United States Attorney for the District of Minnesota attempted to argue that Najarian acted in the interest of furthering his own "personal power and prestige," and blatantly violated FDA regulations for more than twenty years.[22]

After the government rested its case, Judge Richard H. Kyle entered an acquittal judgment on all of the FDA charges. A month later the jury acquitted Najarian on the remaining counts. The outcome of the trial left Najarian a free man, but left many questions open as to Najarian's reputation, the future of ALG, and the handling of the case by the FDA itself. The scathing comments by Judge Kyle at the close of the trial identied many of these issues:

> This has been a long, rough case. I am sure the defendant is relieved with it, but I don't read the verdict as saying that everything that went on with the ALG program was done properly... but the jury has rendered its verdict and that verdict is, as indicated, not guilty... I have some question as to why we are here at all, quite frankly. Not because there weren't things that were wrong with the program, but it was a program that was looked at by the FDA for 15 to

[20] *United States v. Najarian*, Superseding Indictment, No. 3-95-45.

[21] More than 20 people at the FDA had some measure of responsibility for the regulation of ALG during the twenty years of the program. Lundquist, *supra*, note 12, at 914.

[22] Lundquist, *supra*, note 12, at 911.

20 years with what I guess I could describe as benign neglect... converting all of this to a criminal proceeding of the magnitude that we saw here, it seems to me has gone or did go beyond the bounds of common sense. We had a program here in Minnesota which, for all its problems and shortcomings was a good program, literally saved thousands of lives. It should have been run better and it wasn't, but I have serious doubts as to whether that type of program should have been subjected to a criminal proceeding of this kind.[23]

So why did the FDA bring a criminal suit in this case? Skeptics close to Minnesota politics believe that United States Attorney David Lillehaug was looking for political legitimacy in a future governor's race by toppling the well-known surgeon.[24] Najarian himself implied that big business interests in the pharmaceutical industry prompted the FDA to bring the charges. He believed that the producers of the major drugs competing with ALG felt threatened by the success rate and low cost of his drug, prompting them to exert pressure on the agency.[25]

### Implications of the Najarian Case

While it is difficult to assess any political or institutional reasons for the case, it is important to reflect on the implications for future FDA criminal actions and for the interests of the public health in general. While Najarian was permanently exonerated by the court, ALG itself remains in a state of purgatory. The FDA has not lifted its ban on the continued study or prescription of the product, leaving only the higher priced alternatives as legitimate anti-rejection

[23] *United States v. Najarian*, Transcript of February 21, 1996.

[24] Conversation with Montevideo, MN attorney, Stephen L. Stennes, January 21, 1997.

[25] The major competitors with ALG are ATGAM, a similar, horse-derived product manufactured by Upjohn Co., and OKT-3, a product made from mouse cells by Ortho Pharmaceuticals Co.. Sloyut, *supra*, note 13.

drugs.[26] And while Najarian has expressed his wish to bring ALG back into the medicinal mainstream, his scarred reputation will make this a difficult task. In other words, the real losers in this case are not the politically minded government attorneys, but the liver, kidney, and other organ transplant patients who will be denied access to this long used, and seemingly standard, drug.

Perhaps the most interesting paradox in the case involves the interplay between the IND process and the eventual criminal charges against Najarian. He was first criticized and finally indicted in part because of his premature use and sale of a yet-to-be approved drug. The spirit of the IND process itself is to determine the safety and efficacy of a new drug. Over the twenty-plus years that the FDA acquiesced to the use of ALG at the University of Minnesota and other treatment centers, it essentially pushed ALG out of the experimental stage and made it standard therapy. This paradox was identified by Najarian's attorney John Lundquist as follows:

> It is paradoxical and disconcerting that the FDA not only acquiesced in, but also encouraged the widespread distribution of ALG across the country, thus enhancing its status as standard therapy, only to later file criminal charges against its principal investigator because the investigational drug was in fact used as standard therapy. Although not criminally prosecuted, other leading institutions were reprimanded by the FDA for failing to obtain written consent for the use of ALG, even though it was regarded as standard therapy.[27]

This argument was pointed out by the Najarian defense attorneys and appears to have been a substantial factor in Judge Kyle's ruling: "The FDA as I indicate, was certainly aware of what was going on, and yet they came in here as a witness to testify that somehow they were hoodwinked by this defendant

[26] Slovut, *supra*, note 13.
[27] Lundquist, *supra*, note 12, at 913.

and his colleagues and other people at the University."[28] It begs an important question about the implications of inconsistency within the agency over a period of years. With a game of musical chairs involving inspectors during a long-term IND process, how can doctors and institutions involved in research expect to gauge the legality of their programs?

Perhaps more importantly, will surgeons begin to view this specter of criminal prosecutions in the wake of the Najarian case as a deterrent in their development of new drugs? While the FDA failed in sending Najarian to prison, they did succeed in shutting down his operation and ruining his reputation. It would be tragic if future medical visionaries are deterred from taking the same chances Najarian did in his quest for a breakthrough treatment. The threat of further filing of criminal cases by the FDA against new drug investigators is likely to create precisely this effect within the research/medical community.[29] Another concern in the aftermath of the Najarian case is the lack of support from within the surgeon's own institution. Soon after the charges were brought against Najarian, the University of Minnesota turned down a number of overtures from the doctor's attorneys requesting a joint defense agreement.[30] Such an agreement would have left internal investigations and communications between Najarian and the University's general counsel immune from discovery. In

[28] *United States v. Najarian*, Transcript of Feb. 21, 1996, *supra*, note 23.

[29] In his article on the Najarian case, Lundquist further explored this theory with actual quotes from a number of research physicians: "One surgery department chairperson, referring to the 'serious anxiety amongst academic physicians,' predicted a 'reluctance of many good academic people taking on clinical trials knowing that there is this kind of capricious risk of litigation by the government."' Lundquist, *supra,* note 12, at 914.

[30] *United States v. Najarian*, 915 F.Supp. 1460, 1468 (Minn. 1996).

an effort to distance itself from the case, the University declined such offers and took a position adverse to its famous faculty member. This left Najarian to fight these charges on his own, abandoned by the very institution which supported him throughout the history of the ALG program. In an ironic turn of events, the University now faces a lawsuit of its own surrounding ALG and is being forced to adopt many of the same defenses asserted by Najarian in the original case.[31]

***United States v. Stanislaw R. Burzynski***

A Brief History of 'Dr. B' and His Mysterious Cancer Drug

Is the man a quack and a charlatan or a visionary and a pioneer? As the standard-bearer for an American's right to alternative medical treatments in the absence of FDA approval, Dr. Stanislaw R. Burzynski has presented his antineoplastons as important evidence. The debate over this treatment and the issues that go along with the topic have launched a debate straight out of his Texas clinic all the way to Capital Hill. Its most probing questions involve the appropriate role of the FDA in cases in which patients have reached what they believe to be the end of all their available ropes.

Dr. Burzynski first developed antineoplastons in the late seventies. A nontoxic blend of peptides and other amino acids, the drug was originally

[31]On December 19, 1996 the U.S. Department of Justice filed a lawsuit worth more than $100 million against the University over alleged misuse of federal research grants and the illegal sales of ALG. The suit was joined with a whistleblower action filed by a University of Minnesota biology professor who stands to reap a multimillion-dollar windfall in the action. Despite last minute appeals by Senators Rod Grams and Paul Wellstone, Rep. Jim Ramstad, and Governor Arne Carlson, the DOJ refused a settlement offer and filed suit as threatened. Discovery is set to commence this spring.

extracted from human urine but is now manufactured synthetically. As Dr. Burzynski further explains, the antineoplastons "function as biochemical micro-switches, turning off the genes that cause cancerous cells to grow and turning on the ones that supress them."[32] He marketed the drug as an alternative to chemotherapy and radiation, the 'standard' cancer treatments which ravage the bodies of cancer patients and often provide little more than temporary relief.

The Burzynski clinic treated thousands of patients with antineoplastons from 1977 to the present, and he developed a reputation among his patients as a revolutionary lifesaver. The biggest problem, however, with Burzynski's "miracle cure," was that it had not received the requisite approval from the FDA.

### The Criminal Case Against Burzynski

In May of 1983, U.S. District Judge Gabrielle McDonald issued an order that permanently enjoined Burzynski and his clinic from producing and introducing into commerce the antineoplastons. The injunction was to be in place until Burzynski, 1) received an approved IND distinction from the FDA under 21 U.S.C. §355; or 2) received written statement from the FDA that the product did not qualify as a "new drug." Burzynski met neither of these requirements and continued to prescribe and administer the drug to his patients for treatment of many different diseases, including AIDS, Parkinson's, and numerous forms of cancer.[33]

[32] Katz, *supra*, note 3, at A16.
[33] *United States v. Burzynski*, Indictment, No. H-95-290, p. 8.

After a series of private lawsuits against Burzynski, the Department of Justice brought a criminal indictment against him for contempt of a federal order, 34 counts of mail fraud,[34] and 40 counts of violating the federal food and drug law. The FDCA counts allege that Burzynski and his clinic introduced into interstate commerce large quantities of an unapproved drug without approval of an application filed under 21 U.S.C. §355.[35] Burzynski faces up to three years in prison and a $250,000 fine on each FDCA count and up to five years in prison and a $250,000 fine on each mail fraud count. The sentence for contempt lies within the discretion of the trial judge.[36]

While the issues in the *Najarian* case have been litigated already, the most legally important chapters of the Burzynski story are yet to be written. The trial started earlier this month in United States District Court in Houston. Despite an early setback in which the court ruled that the issue of the effectiveness of antineoplastons was not an issue for the jury,[37] Burzynski's attorneys remain optimistic that he will emerge a free man. While they have indicated they will not dispute that Burzynski sold and distributed the drug, they will argue

[34]The mail fraud claims allege that Burzynski attempted to defraud insurance companies by using improper Current Procedural Terminology Codes (CPT Codes), misstating the medications prescribed to patients in order to get the costs reimbursed. *United States v. Burzynski*, Indictment, *supra*, note 33, at 16.

[35] *United States v. Burzynski*, Indictment, *supra*, note 33, at 13.

[36]Bruce Nichols, *Jury Told Doctor Delivered Drug Illegally*, Dallas Morning News, Jan. 8, 1997, p. 19A.

[37]Burzynski's attorneys argued vehemently that it is unfair to keep the issues of the drug's efficacy from the jury, and that the doctor could not receive a fair trial without this important evidence. After considering the briefs from both sides, however, Judge Sim Lake reasoned that, "This is not a wrongful death suit. Whether the drug worked or did not is not relevant." He ruled that certain testimony from former patients as to the effectiveness of the drug would be allowed only if Burzynski attempts to adopt a "necessity defense." Such a defense inplies that a life-threatening situation arose which prompted someone to break the law. It is unlikely, however, that the defense attorneys will attempt to make such a claim. Deborah Tedford, *Doctor Loses Round in Court,* Houston Chronicle, January 3, 1997, p. 29.

that his intent was never wrongful. "The medical oath requires that doctors first do no harm," said John Ackerman, Burzynski's attorney, "and (Dr. B.) believes that to withhold antineoplastons is to do harm."[38] Attorneys for the government will hold firm to their contention that Burzynski never asked for nor received the appropriate FDA approval for the drug.

### The Bigger Issues Involved

While the outcome of the trial will not be clear until later this winter, the issues raised by the compelling saga of the Texas cancer doctor are ripe for debate. By shutting down and criminally punishing Burzynski is the FDA performing its mission to protect the public health? Or, is the agency essentially denying a medical treatment of last resort merely because the provider of that treatment failed to comply with the strict bureaucratic rules of the approval process?

"This truly is a matter of life or death,' said Steve Siegel, the husband of one of Burzynski's patients. "My wife will die without this treatment."[39] Other patients echoed such statements: "What right do they have to tell me that we can't come down here and be cured?" questioned Ric Schiff, the father of six-year-old patient Crystin Schiff, who died in 1995 as a result of what he believes were massive doses of ineffective chemotherapy and radiation. "If those are your other choices, which one do you choose?" he asked. "Who is the FDA protecting us from?"[40]

[38]Nichols, *supra*, note 36, at 19A.
[39]Tedford, *supra*, note 37, at 29.
[40]Katz, *supra*, note 3, at A16.

Officials at the FDA argue that they have a strong interest in protecting the public from "cancer quacks" who prey on desperate patients during their final hours. The agency has a long history of engaging in litigation with producers of unapproved cancer treatments, must notably the drugs Laetrile and Krebiozen in the sixties and seventies.[41] Officials at the agency truly believe strongly in their responsibility to protect the consumer from false claims by "snake oil salesmen."

### From Populist Rhetoric to Political Debate: The Case Goes to Washington

When it comes to remedies for cancer and AIDS, this clash of agency concern and human choice becomes most thorny. This debate was propelled onto Capital Hill last term with proposed legislation called the "Access to Medical Treatment Act." The proposed bill specifies that an individual can be treated with any medical treatment the individual desires, if: 1) the practitioner agrees to treat that individual; and 2) the administration of such treatment does not violate state licensing laws. It gives healthcare providers the option as to whether to pay for nonapproved treatments.[42] In response to consumer protection concerns raised by opponents of the bill, proponents, such as Widener University Law Professor Michael Cohen, argue that, "[T]he bill permits only treatments provided by legally authorized providers and that do not unreasonably and significantly

[41] *See, e.g., Tutoki v. Celebreeze*, 375 F.2d 105 ($7^{th}$ Cir. 1967); *Rutherford v. American Medical Ass'n*, 379 F.2d 641 ($7^{th}$ Cir. 1967); *United States v. Hotsey Cancer Clinic*, 198 F.2d 273 ($5^{th}$ Cir. 1952).

[42] *Access to Medical Treatment Act,* S#1035.

alter patient health. It incorporates informed consent requirements... and also prohibits false or misleading labeling and forbids commercial advertising."[43]

The hearings held in the Senate involving the bill involved many of the major players in the Burzynski case. Among those testifying were Shawn and Desiree McConnell, of Fountain Hills, AZ, the parents of 7-year-old Zachary McConnell, a patient who was given permission by the FDA to intially use antineoplastons, only to find the drug "yanked away" months later.[44] In a prepared statement, Mr. McConnell made a passionate and compelling case for the bill:

> I realize that my son's treatment is "controversial" because of things that have nothing to do with the medicine's abilities, but with lawyers and rules which govern the WAY a drug is approved. That is irrelevant, because to seek curative measures on their own should be encouraged. But current FDA law looks upon us all as desperate minions too stupid or confused to think for ourselves... The essence of the case for this bill lies in safety vs. efficacy. Safety is an issue of public health, and a fine assignment for FDA scrutiny. Efficacy, however, is consumer awareness. We are not judging CD players or fat-free cookies here. Profound and private, life and death decisions are on sacred ground. The FDA is out of place here... Lab scientists do not treat people in need (emphasis in original).[45]

In perhaps an even more impassioned plea, young Zachary McConnell brought with him to the hearing a letter he wrote to President Clinton, which said: "You should fire the man who won't let me have my medicine... I don't want to have cancer anymore."[46]

On the other side of the argument, the bill was opposed by the FDA and

[43] Sue A. Blevins, *Legalize Alternative Medicine,* Christian Science Monitor, March 28, 1996.

[44] Zachary originally qualified for a "compassionate exemption" due to the seriousness of his brain tumor, but the FDA rescinded the exemption shortly thereafter.

[45] *Access to Medical Treatment Act, Hearings on S#1035 before the Senate Labor and Human Resources Committee*, July 30, 1996 (testimony of Shawn McConnell).

[46] Jeff Barker, *FDA 'Playing God,' Parents Say Cancer Drug Sought for Ill Son,* The Arizona Republic, July 31, 1996, p. A1.

many consumer groups for fear that it would open the door for aggressive doctors to sell off-the-wall medications to desperate patients, simply in order to make a buck. They also argued that the necessary levels of safety of drugs would be less certain under such a regime, lacking in adequate safety testing.

Despite the support of powerful lawmakers on both sides of the aisle, the bill has yet to reach the floor of either house.[47] It is certain to come up again during this session of congress and will likely receive even more serious consideration. The court's findings and the popular reaction to the *Burzynski* case are likely to play a substantial role in the manner in which the political process muddles through this debate.

## The Big Picture: Lessons From *Najarian* and *Burzynski* Regarding FDA Policy

Dr. Najarian is attempting to rebuild his reputation in the aftermath of the acquittal and Dr. Burzynski is currently fighting for his life in U.S. District Court. Even though the dust is far from settling in these cases, there are clearly some important lessons to be learned from this brief case study:

1) The threat and use of criminal charges against research physicians has created an "us versus them" attitude which could prove to be the real danger to the public health.

It is clear that the Najarian case could have a substantial chilling effect on academic surgeons interested in participating in the field of new drug develop-

[47] Supporters of the bill included Sen. Tom Daschle (D-SD), Sen. Bob Dole (R-KS), Rep. Peter DeFazio (D-OR), and Rep. Joe Barton (R-TX). Blevins, *supra,* note 43.

ment. The fear that even 20 years of FDA acquiesence to a program might not be enough to render a new drug development safe from criminal prosecution is a likely deterrent from the perceived risks of entering the field.[48] Academic surgeons also argue that the increased risk of criminal liability further tips a scale already weighted toward large pharmaceutical companies by the $400 million cost of taking a new drug from discovery to the market.[49]

Anytime innovation is stunted in the new drug field, the real loser is the public health. The wildly creative antineoplastons and ALG's of today might be the Salk vaccines and penicillins of tomorrow. There is no question that fraud and mismanagement can occur over the course of a new drug development. As Judge Kyle indicated, there is no doubt that there were problems with Minnesota's ALG program. The FDA needs to realize, however, that more interactive and consistent oversight, combined with the threat of civil sanctions, is a better manner in which to deal with new drug development without stunting innovation.

2) There are clear problems with the bureaucratic structure of FDA oversight which must be ameliorated in order to improve the new drug process.

Perhaps the most disconcerting feature of both cases centers around the

[48] A fear has also been expressed that the FDA has a tendency to buttress FDCA charges with other criminal allegations in order to strengthen the legitimacy of a case. Judge Kyle even commented in this issue at the close of the *Najarian* trial: "[S]omehow this combined in an indictment which probably should have focused only upon the ALG and FDA program, but was added on to with charges of tax fraud, mail fraud, embezzlement and stealing. I think in football you kind of call the penalty for piling on. And that's what I thought this was." *United States v. Najarian*, Transcript of Feb. 21, 1996, *supra*, note 28.

[49] Blevins, *supra*, note 43.

inconsistency of FDA oversight and the mixed messages sent to Najarian and Burzynski over the years. As indicated above, Najarian dealt with more than 20 different FDA inspectors during his tenure and was clearly confused by the mixed messages sent regarding the efficacy and legality of the program. He was told all of the following: first, "Sell ALG;" then, "Don't sell ALG;" followed by, "Sell it only up to cost;" then finally, "Quit making the drug altogether (even though it had become standard fare in the entire transplant community)."

Burzynski's neoplastons received their own measure of inconsist treatment from FDA. Six years into production he was enjoined from selling the drug at all, only to be given permission to run clinical studies to prove its efficacy a few years later. Finally, the plug was suddenly pulled on the drug altogether,[50] leaving one patient to remark that, "I am in a war against cancer and the government keeps trying to take away the only weapon I have."[51]

The FDA needs to streamline the oversight process as currently conducted by its field agents. It is vital that a single inspector (or as few as possible) develop a sense of familiarity with a program and speak with one voice as the FDA's mouthpiece for each particular drug development. As Inspector Wayne Schafer testified in the Najarian trial, "[T]he bureaucracy is so prone to turnover that the right hand does not always know what the left hand is doing."[52] Only

[50]Only approximately 300 of what were formerly thousands of patients are allowed to be treated currently under very close FDA scrutiny.

[51]*Rebel Cancer Doctor Goes on Trial for Fraud*, Chicago Sun-Times, Jan. 6, 1997, p. 19.

[52]David Peterson, *In Najarian Trial, Inspector Cites FDA Inaction,* Minneapolis Star-Tribune, Jan. 31, 1996.

with consistency will the bureaucratic bumbling evident in the Najarian and Burzynski cases be avoided.

3) There are some basic philosophical issues regarding the FDA's unclear mission with regard to issues of access to alternative medical treatments.

The FDA enforces its IND and NDA (New Drug Application) programs in order to protect the public from unsafe and ineffective drugs. This is indeed an important and admirable mission - one that few people will argue should be changed. But what of the claims of a real public health interest when people are faced with a terminal illness? As is clear from a study of the Senate testimony, many believe that the real health concern is free access to whatever treatment a terminally ill individual believes might save his or her life. There is a fundamental clash here which can best be reconciled through legislative means. The bipartisan bill proposed last term is a step in the right direction, but our elected representatives must make a clear statement as to the FDA's mandate in the realm of alternative medicine. Only after a vote on the Access to Medical Treatment Act can this issue be truly resolved.

4) With the limited resources of the agency and the push for further streamlining of the regulatory process, those physicians who enter the new drug area must carry an even higher burden than normal when it comes to the ethical and industrious production of new drugs.

The first three "lessons" place the burden on the government to deal with these issues. It would be unfair, however, to place all of the burden on the public servants. In this era of "downsizing," "reinventing government," "devolution of

power to the states," and "lower taxes," it is inevitable that the public sector will lose some of its bark and bite. It is incumbent, therefore, that private individuals and corporations shoulder even more personal responsibility than ever before: In new drug development this means that investigators must keep increasingly clear and more accurate records; those taking the hippocratic oath must realize that they bear a responsibility to look beyond dollars and maintain their common sense; the free press must continue to serve its function as an oversight mechanism and alert the public to abuses in the system; and the large research universities which play host to many of these studies must not lose sight of the activities going on in their laboratories and hospital rooms.

## Conclusion

The *Najarian* and *Burzynski* cases certainly have their differences. Other doctors came to Najarian for access to his controversial drug, while Burzynski aggressively approached desperate patients with his. Najarian was viewed as a giant of the industry and a major player in the mainstream medical establishment prior to his FDA charges, while Burzynski has always been considered a bit of a radical and a populist hero. Najarian attempted to use the IND process for his own personal gain, while Burzynski maintained a fundamental disbelief in the FDA approval system altogether. These differences, among others, make it clear that an acquittal in the Burzynski case is not a foregone conclusion.

For all their differences, though, the sagas of these two doctors illuminate

some important issues with regard to the status quo of Food and Drug Administration policy. In order to truly act in the interest of public health, the agency needs to improve the way in which it deals with the creative and brilliant minds who are developing the new drugs of tomorrow. The continued threat of criminal prosecutions as used against research physicians and the stringent application of bureaucratic pressure to deny desperate patients of hopeful treatments are not the most effective ways to chart a course toward the FDA's public health and safety mission.