Legal Matters

# For the Defense of ACM

## *An Interview with Rick Jaffe, Esquire*

**Alan Dumoff, J.D., M.S.W.**

*AUTHOR'S NOTE: I had the pleasure of interviewing Rick Jaffe, Esquire, perhaps the most eminent litigator providing his services to the alternative and complementary medicine (ACM) professional community. Mr. Jaffe is best known for defending Stanislaw Burzynski, M.D., against a two-decade ordeal and onslaught of multiple federal, state, and insurance company racketeering lawsuits and investigations that attempted to put Dr. Burzynski out of business and into jail.*

*These cases culminated in a 75-count federal criminal indictment alleging Food and Drug Administration (FDA) violations and insurance fraud. The indictment could have carried a virtual life sentence for Dr. Burzynski, if he had been convicted. The federal government tried to convince two juries—the first trial ended in a hung jury—that Dr. Burzynski was a menace who purveyed fraudulent, unapproved cancer therapies on a gullible public.*

*With Mr. Jaffe and his handpicked team of attorneys in the courtroom, and a grateful public gathering outside, Dr. Burzynski was acquitted, and as a result, Dr. Burzynski continues to provide antineoplastons via clinical trials along with other therapies in his Houston, Texas, clinic.*

*But this is hardly Mr. Jaffe's only contribution to the right of practitioners to provide reasonable therapies outside of the mainstream. A central legal principle in the defense of practitioners who provide alternative and complementary therapies—and one that I have cited many times in briefs as well as past articles—is the concept of assumption of risk.*

*If a patient knowingly and voluntarily assumes the risk of foregoing conventional care and instead chooses ACM, then as a matter of law that person should not be able to recover against the ACM doctor because the patient assumed the risk of such treatment. Without such a defense, ACM practitioners can be particularly vulnerable to legal challenges by professional boards or in malpractice action because the ACM treatment is by definition a departure from the so-called "standard of care."*

*As I have repeatedly told my clients, privately—and as I often publicly state in my articles and lectures—when properly prepared informed consent forms are signed by a patient, which gives the patient notice of the nonstandard nature of the care, and notice is given about the risks of such care of the damage suffered, this may be the basis of a court holding or a jury verdict that the patient knowingly assumed the risk of the therapy and cannot recover from the practitioner if such a problem does arise.*

*Well, that may be the law now, but it was not always. Although assumption of risk was an established principle in English and American common law, it had not been accepted as a defense against a medical malpractice claim because of the imbalance of information between a physician and the patient. That is until Mr. Jaffe and other attorneys at his firm convinced the Federal Second Circuit Court of Appeals that patients can obtain enough information to make an informed choice of treatment, and as a result, the patient should not be able to recover if he or she assumed the risk of unconventional treatment. The case was Schneider v. Revici,* the year was 1987, and since that time, thanks to Mr. Jaffe and his team, practitioners and their attorneys can and have used this case as a basis for asserting an assumption-of-risk defense to a medical malpractice suit.*

**Alan Dumoff: Where did your interest in defending ACM practice come from?**

**Rick Jaffe:** One prime motivating factor was that I did my undergraduate and some graduate work in the history and philosophy of science, which is basically how knowledge grows and advances. Although I liked the intellectual endeavor, being full time in an academic setting was too much for me. I wanted to get out into the world, so I went to law school, and within a few years after graduating, I started a law firm with a friend of mine, Sam Abady.

Our first case in this field was the Revici malpractice lawsuit in the mid-1980s, and since we made new law, we started getting more and more cases. I was drawn to these kinds of cases because of my background.

You know, Alan, I think that what you and I do for a living is pretty much applied philosophy of science. We're dealing with people who are trying to advance medical science. Some succeed; some fail. They're right sometimes, often wrong, and, many times they violate some statute or policy, or sometimes

*Schneider v. Revici, M.D., and Institute of Applied Biology, Inc., 817 F.2d 987; 1987 U.S. App. LEXIS 5725; 22 Fed. R. Evid. Serv. (Callaghan) 1493.

they just tick off the wrong bureaucrat. You, me, and a couple of other attorneys like us are out there in the trenches helping them do what they do. All in all, it's a pretty good way to keep busy.

I guess my father was also a big influence. He's a New-Ager kind of a guy. He was a macrobiotic, vegan, Buddhist, and he does a lot of other stuff like that. He took me to Esalen [Big Sur, California] and got me to do TM [Transcendental Meditation™] and EST [Erhard Seminar Training]. He's been to Finhorn in Scotland and communed with the plants. He treated many of his own medical problems with herbs and other natural remedies, and always talked about the latest miracle supplement or alternative ray machine or the like.

Sometimes he'd go too far, like when he used cabbage leaves to treat his hernia. But by and large he had the good sense that for life-threatening events, he went with the conventional route when that was clearly the best way to go, like bypass surgery when he had multiple 90 percent coronary occlusions, or surgery for stage 1 colon cancer.

As an aside, let me say that I've seen many people embrace alternatives so intensely and mindlessly that they lose sight of the need to use conventional medicine when it works, and needless to say, not all ACM practitioners are up there with Albert Schweitzer.

**AD: I think I have an idea of what you mean [grinning], but could you amplify?**

**RJ:** O.K., there obviously is a wide range and variation amongst ACM practitioners. There are a few geniuses, many, many smart, dedicated and competent practitioners, but there are also a lot of folks out there that are pretty marginal or worse.

The other complicating factor is that obviously things change over time, meaning some things that appear wrong or crazy eventually prove out. I use the Schopenhauer quote sometimes in my cases. It goes something like: "There are three stages of truth: first it is reviled, then ridiculed, and finally it is accepted as commonplace."

**AD: Pretty good.**

**RJ:** Yes it is, but we also have to be mindful of the logical fallacy of assuming that just because an idea is reviled or ridiculed doesn't mean that it will be accepted as true and commonplace. History has taught us that there are plenty of crazy medical theories, and an abundance of treatments and devices that don't and shouldn't make it past Schopenhauer's second stage.

And that directly translates into the patient decision matrix. For example, a patient with a small breast carcinoma *in situ* who forgoes surgery for an herbal treatment isn't making a wise choice, and a doctor who would make such a recommendation will likely get into trouble, at least at the medical board level, regardless of what any lawyer, statute, or case says. And that will be the case until there is some fully tested, better, and approved less-invasive treatment.

**AD: I recall hearing similar sentiments at the Office of Technology Assessment [OTA] meeting on alternative cancer treatments way back in 1990. I understand you played a role in that process. What was that experience like?**

**Top: Mr. Jaffe delves into deep waters; at right: Rick Jaffe, Esquire, Houston, Texas.**

## About Rick Jaffe

Richard (Rick) Jaffe, Esquire, graduated from the Hebrew University of Jerusalem, Israel, with a B.A., with honors in 1975, and from Columbia University School of Law, New York, New York, in 1979, where he was a Harlan Fiske Stone Scholar and a member of the board of editors of the *Columbia Law Review*. Since 1991, he has been based in Houston, Texas, and handles health care investigations and litigates matters throughout the United States. His full *curriculum vitae* may be found on his website at: www.rickjaffeesq.com

To contact Mr. Jaffe:

3100 Phoenix Tower
3200 Southwest Freeway
Houston, TX 77027
Phone: (713) 626-3550
Fax: (713) 626-9420
E-mail: info@rickjaffe.com

**RJ:** That was a very contentious process. Parenthetically, I have to thank my wife for letting me go because my daughter Rebecca was born a day or two before the meeting, and my attending the meeting meant that I wasn't there to bring them home from the hospital.

Anyway, you were there also, so you probably recall that police were at the meeting in force because of concerns that emotions would get out of hand. I spoke primarily on the OTA's assessment of Burzynski. But because of my experience in litigating against insurance companies, which routinely denied reimbursement for CAM treatments, I also spoke on, and eventually had a hand in preparing, the final version of the insurance reimbursement section of the OTA report.

**AD: Do you think the process and report were good for the field?**

**RJ:** Definitely. The report was an important first step, and I think it eventually and probably directly led to the creation of the Office of Alternative Medicine, for whatever good that did.

**AD: It was also quite a learning experience.**

**RJ:** It was a volatile process and the ACM people treated it with not undeserved mistrust and skepticism.

**AD: Having gone to law school a little later in life, and seeing students fresh out of undergraduate school learning a**

**rather stilted philosophy of life from law professors, I've always thought that a little seasoning is important before law school. You spent several years in Israel and went to yeshivas prior to law school. Tell me a little about your path.**

**RJ:** I went to college in America for a year and half, dropped out, went "On the Road" with Kerouac and started my "Journey to the East" with Hesse. First stop was Israel. I planned on continuing; I had planned to go to India after spending a year in Israel, but never got past Jerusalem. I studied in a yeshiva for a while, then transferred to the Hebrew University of Jerusalem, where I got my B.A. and spent some time in graduate school, and working in Jerusalem before returning to America to go to law school.

**AD: How did you like living abroad?**

**RJ:** Spending 5 years in Israel from my late teens was generally a positive and rewarding experience, but many years in Israel caused me some cultural identity confusion. Israelis called me the "American" but even after I returned to America, I wasn't completely comfortable for many years.

I guess this personal path in conjunction with my philosophy of science background and my father's New-Age approach to aging and health crises gave me a good foundation and appreciation for the cutting-edge, experimental health care issues that I've worked on for the past 20 years.

But I have to say what I enjoy most is being where the action is; for me it isn't academic anymore, but it's about being in the courtroom, litigating, bringing a thoughtful approach about how we make scientific judgments to conflicts about how doctors and patients get to make choices and explore innovative options, whether it's developing new biologic agents or something institutional science may consider nonsense, but may help some people feel better.

**AD: You've accomplished a great deal in the courtroom. Much of the intensity of these cases doesn't necessarily come through in the written opinions. What experiences come to mind?**

**RJ:** I appreciate the acknowledgment, but I have to tell you that although I've had my ups and down in court, as someone who is primarily a defense attorney, when I finally get to court, you will probably also see a long trail of my fingernail marks, as in, they usually have to drag me kicking and screaming before you will see me at a trial or board hearing.

A prominent Houston criminal defense once told me: "If you have to actually go to court, you're already in bad shape." So to be frank, as a defense attorney, I'll do anything reasonable (and sometimes, some pretty unreasonable or crazy things) to avoid having some judge or jury decide a case on the merits. Oftentimes, settling and not going to trial is the best and most cost-effective way to resolve legal entanglements, especially since much of the time, the practitioner or company has done something which is at least arguably in violation of some law. So as ironic as it may sound, my first rule as a defense litigator is, if at all possible, avoid going to court.

**AD: I agree and feel the same way.**

**RJ:** There's a corollary to this rule that I tell my clients in the form of a joke. In the Middle Ages, there was a court jester named Moishe. He had the good fortune of having an affair with the beautiful queen of the realm, but the bad luck of having the affair discovered by the king. He was brought before the king, who ordered his head chopped off. To make a long joke shorter, Moishe convinced the king that he could teach the King's horse to fly in 2 years. But the king said that if his horse didn't fly in 2 years, Moishe would be savagely tortured and would wish that he had been executed earlier.

As Moishe was taken away to pick his bride and new house (he had also convinced the king that he needed both to be able to do the job), his assistant Yankel came up to him and said: "Moishe, what have you done, you know damn well you can't teach the king's horse to fly, and so you're going to have a horrible, excruciating death. What have you done to yourself?"

Moishe rubbed his chin, looked at Yankel and said: "Look, a lot could happen in 2 years. The king could die of natural causes. I could die of natural causes. The horse could die of natural causes, or maybe even I could even teach the horse to fly. At least I got past today, and we'll see what happens down the road."

**AD: I got it, good joke.**

**RJ:** But that joke being said, sometimes you have drawn the line and sometimes you have to go to court or to a hearing and like any trial attorney, I've had my moments.

**AD: Care to share any?**

**RJ:** Well, since you've twisted my arm (no small feat in a telephone interview!). . . .Like a lot of trial attorneys, I've had some of my best moments on cross-examination.

During the Burzynski criminal trial, I was cross-examining the main FDA witness, and trying to get across the point of how big and mindless the FDA was, and that it would have been impossible for Burzynski to have his drug approved by the FDA.

In talking about the benefits of the careful and lengthy drug approval process, he said that if aspirin had to be approved under the FDA's current safety and efficacy standards, the FDA would not have approved it. The judge was taken aback, and asked him, "you don't really mean that aspirin would not be approved today by the FDA, do you?" But the FDA official stuck to his guns and insisted that aspirin would not be approved by the FDA because it's not safe and there are better things out there.

In a small bit of theater, I then turned to the judge and jury, held up my hands, in astonishment and said "judge, I rest my case." That got a big laugh, and I think the exchange made an impression with the jury.

Probably the most accomplished physician I ever represented was the late Hugh Fudenberg, who was a classical immunologist and edited one of the main textbooks on immunology used in medical schools. He was brought before the South Carolina Medical Board on charges arising from his use of an experimental treatment called "transfer factor."

The board's expert was an allergist (i.e., not a classical immunologist); he was, however, the world's expert on slime mold, and I repeatedly referred to his expertise in that area. He doggedly maintained that he was very competent to opine that Fudenberg mistreated his patients (by giving them transfer factor under

# The Burzynski Litigation

*A Case Study in Your Kafkaesque Government at Work*

Rick Jaffe, Esquire, is probably best known for his successful defense of Stanislaw Burzynski, M.D., against numerous state and federal civil and criminal lawsuits over the past 20 years; Mr. Jaffe headed the legal team that obtained an acquittal or dismissal of all 75 counts of a criminal insurance fraud and Food and Drug Administration (FDA) indictment.

Dr. Burzynski had developed his approach to cancer, termed "antineoplastons," while a researcher at Baylor College of Medicine, Houston, Texas, in the early 1970s. In 1983, the FDA sought to close his clinic.

The State of Texas joined the fray in 1988 by trying to revoke his medical license, and in 1992 the Texas State Attorney General's office added another lawsuit and bought suit against Dr. Burzynski in 1992, charging that he was treating patients who had cancer with an unapproved drug.

Three federal grand juries failed to indict but in 1995, a fourth grand jury indicted Dr. Burzynski on 75 counts including mail and insurance fraud and violating prohibitions of using unapproved drugs in interstate commerce. Mr. Jaffe hand-picked and headed the legal team that obtained an acquittal or dismissal of all 75 counts.

The fight between Dr. Burzynski and various government agencies was long, loud, and often acrimonious, and played out in a variety of venues. During several of the grand jury terms, Mr. Jaffe claimed the government employed a variety of unfair and possibly illegal tactics.

For example, Mr. Jaffe developed evidence that prosecutors may have leaked secret grand jury testimony to attorneys for a large insurance company who was itself involved in litigation with Dr. Burzynski. This leak was part of the basis of a federal racketeering lawsuit filed by Mr. Jaffe on behalf of Dr. Burzynski. Shortly after the case was filed, the lead prosecutor left his job and moved out of state.

During another grand jury term, the government subpoenaed Harris County Attorney Mike Driscoll, who was on Dr. Burzynski's board of directors. In retaliation to his supportive testimony before the grand jury, Mr. Jaffe believed the government made it look as though it was initiating a separate grand jury investigation of Mr. Driscoll for possible illegal campaign contributions.

Other questionable subpoenas included one to Ralph Moss, M.D. (a noted proponent of fair evaluations of alternative and complementary medicine cancer therapies) and for all of Dr. Burzynski's patient records. In part, due to the adverse publicity arising from these unfair tactics, the government's prosecutor was removed from the case and reassigned out of the trial division.

After Dr. Burzynski was indicted, the FDA at first failed, and then succeeded in convincing the federal judge to prevent Dr. Burzynski from treating any of his patients until the criminal case was resolved! Mr. Jaffe and Burzynski supporters convinced Congress to hold emergency hearings on this, and eventually, Congress convinced the FDA to put all of Dr. Burzynski's current and future patients on FDA-sponsored clinical trials.

So while one part of the FDA was trying to put Dr. Burzynski in jail, another was overseeing clinical trials on the very same drugs that were the subject of the criminal prosecution.

Perhaps the best view of the trial comes from excerpts from a letter one of the jurors sent to Janet Reno, United States Attorney General at the time:

> Dear Attorney General Reno,
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> I was recently a juror on a Federal trial in Houston, Texas. . . .This letter is to inform you of how upset I am at how my time and tax dollars were wasted on this trial.
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> This case, which began on January 6, 1997, involved the FDA and their apparent anger at Dr. Burzynski for continuing to make available his unapproved new drug, Antineoplastons, to persons living out of the state of Texas. . . .
>
> A second reason I feel this case should not have gone to trial is because while the trial was going on, the FDA had already approved 71 clinical trials, thereby allowing Dr. Burzynski full release to ship Antineoplastons to persons living out of the State of Texas. This was not known to the jurors at the time. After the trial ended, I gleaned this information and felt I had been involved in something that was a ridiculous waste of two months of my life. After all, wasn't this a moot point at this time? Surely our government has real "criminals" to prosecute. . . .
>
> In addition, the prosecution failed to introduce even one witness who could say anything defamatory about Dr. Burzynski's character. One would think after four years of preparing for this trial they would have found at least one disgruntled patient, former employee, business associate, or colleague who had something negative to say about him.
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> Also, since the prosecution had been working on the case for four years, I expected the exhibits, witnesses and evidence to be compelling. It was not, and they didn't come close to proving their case.
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> Since the trial I have learned much about the history of this man and the attempts by the FDA to shut him down. It is my heartfelt belief that a person confronting a life-and-death situation, either for himself or for a dependent child, should be allowed to make these tough decisions himself. Once the FDA has said that a drug is non toxic and that it will not harm a person (which they had), it should be left up to the patient to choose what he or she feels is the best treatment available. The FDA should be supporting Dr. Burzynski in his valiant effort to cure and ease the suffering of cancer patients. Incredibly promising results have taken place already with the remission of brain tumors, non-Hodgkin's lymphoma, and breast and prostate cancers. The lives and quality of life of cancer patients should be uppermost in the minds of the FDA—not what rules were allegedly broken in the past.
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> Since the end of the trial, I have done independent research and have learned many disturbing facts about the FDA's "antics" in this case. Some notable incidents are:
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> - The FDA convened four or five different grand juries before the last one agreed to indict Dr. Burzynski.
> - On two separate occasions the FDA confiscated a total of 300,000 documents (ie, patient records, MRI scans, progress charts, etc) and for Dr. Burzynski to be able to continue to treat his patients, he had to purchase a Xerox machine, install it at the FDA office, hire someone to make copies, and to make it even more difficult, he was required to call a day in advance to make an appointment for copies to be made. To this day these documents have not been returned.
> - Amy Lecocq, the lead prosecutor in this case, violated at least six federal laws governing subpoenas of journalists when she subpoenaed a Dr. Richard Moss. When he pointed this out to her, she withdrew the subpoena.
> - Patients and their families met with the House Commerce Subcommittee on Oversight and Investigations, headed by Representative Joe Barton of Texas. After hearing the collective plight of these brave people and also hearing from Dr. Burzynski's lawyer, Rick Jaffe, Rep. Barton used the word "vendetta" in describing the actions of the FDA over the past 12 years in regards to Dr. Burzynski. I would agree with this assessment.
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> I do feel so very fortunate to have been allowed the opportunity to serve on a federal jury and would do it all over again. I saw first hand that our system of trial by jury, which says that a person is innocent until proven guilty, does work, and for this I will always be grateful.
>
> Sincerely,
>
> L. Darlene Phillips

an FDA IND [Investigational New Drug]). But he finally admitted that he would not have treated a single one of Fudenberg's immunologically impaired patients because he didn't have sufficient experience with these conditions. We did all right in that case, in large part because of the expert's admission.

But of course sometimes, it's what you do before a jury hears the case that is critical.

I ran into quack buster extraordinaire Victor Herbert in the Schneider v. Revici* case. He killed us as a rebuttal witness during the trial and called Revici "one of the cruelest killers in the world."

I had a chance to pay him back after the case was reversed on appeal on the assumption-of-risk issue. After doing some research, I learned that he engaged in self-experimentation with folic-acid deprivation. His self-experimentation helped establish that folic-acid deprivation could cause impairment of judgment.

I got to depose Herbert in connection with the scheduled retrial. After a couple of hours of him telling me what an important scientist he was, I started asking him questions about his mental problems. He refused to answer, so we stopped the deposition and we went before the judge on my motion to compel him to answer. I guess we got the judge on the right day, because he accepted my argument that Herbert might be mentally incompetent to render testimony due to his impaired judgment, arising from the self-experimentation on folic-acid deprivation and impairment of judgment.

The judge apparently had a good sense of humor. He ordered Herbert to answer the questions, and he also ordered that the deposition take place before a federal magistrate so that the magistrate could determine if Herbert was mentally competent to testify.

We received word the next week that Herbert would have to withdraw from the case because of other important commitments, and then the plaintiff walked away from the $525,000 judgment instead of going forward on a retrial. That was certainly a nice moment, and it also demonstrates the application of defense Rule Number One: Avoid trials (or retrials, in this case) if at all possible.

Of course, most litigation is just a lot of slogging away at paperwork and preparation of witnesses and cross-examinations. But it does have its moments.

**AD: These cases take an awful toll on practitioners. The Revici case took 10 years from beginning to end. Any advice for practitioners on avoiding these problems?**

Well actually, I've read some of your articles, and to give credit where credit is due, if practitioners would just follow what you tell them in terms of recordkeeping and proper informed consent, they would be much less apt to get embroiled in legal entanglements.

I also like the "legal audit" idea that you advocate, which gives the docs a better understanding of how their practices measure up against medical/legal standards. I don't do much of that kind of work; I'm more of an action guy, and frankly, there are people out there who can do a better job than me on this type of work, and I'd say that I'm talking to one of them now.

**AD: Well, thank you. I guess the reason I feel so strongly about legal audits and in general about preventative legal care for ACM physicians is that health care is intensely regulated and highly scrutinized by many levels of government and private parties (plaintiffs' malpractice attorneys being high on the list). It seems to me that it's worth the effort to ensure that the ACM practitioner is practicing as safely as possible. Unfortunately, many practitioners believe that health care freedom is an intrinsic right that gives them rights outside the legal arena, and so they avoid taking steps that might make their practice more defensible, such as consulting with a lawyer.**

**RJ:** Couldn't agree more.

**AD: What is on your plate these days?**

**RJ:** I've got an array of cases around the country. I do a lot of medical and chiropractic licensing cases; I also am working on a number of criminal investigations and indicted criminal cases involving practitioners and companies making supplements and other products. Some involve FDA issues, other cases are for unlicensed practitioners accused of practicing medicine without a license, and I do a fair amount of insurance fraud defense, which is a bigger problem for practitioners since HIPAA [Health Insurance Portability and Accountability Act] federalized all health care fraud. I have also recently been involved in some investigatory work on the use of stem cells and umbilical cord blood.

Speaking of investigations, you've probably had the same experience as me: Many of the best things I've done in the field never see the light of day.

**AD: I've experienced the same thing, but tell the readers what you mean.**

**RJ:** All criminal or administrative cases start out as investigations. Sometimes if I or some other attorney is hired early enough, the investigation for one reason or another doesn't get any traction and doesn't result in an indictment or a formal board complaint. I like to get a case early on in the investigation process.

**AD: You're probably best known in the ACM community for your defense of Dr. Burzynski, one the government had a hard time getting traction on through the first three grand juries, but they were certainly persistent. How is Dr. Burzynski doing? What is his legal status?**

**RJ:** Fortunately, Dr. Burzynski's extensive legal troubles are behind him. He is completing a number of FDA clinical trials, and he is in the process of submitting an NDA [New Drug Application] and orphan drug applications. Many of the studies have shown excellent results, and in the past few years he's been thinking about his drugs in the context of antiaging.

**AD: What do you think are the best ways to advance health freedom?**

**RJ:** Well, let me start with hasn't worked and won't fly in the future: The idea of a judicially created constitutional right to non-FDA treatment is a nonstarter. The Supreme Court hasn't accepted it in the past. If we couldn't make it happen with the Supreme Court justices we had 25 years ago (in the laetrile case, Rutherford v. U.S.),† we surely will not be able to convince the current justices to expand personal constitutional privacy rights. And I know about Benjamin Rush's oft-quoted statement that the

framers assumed that people had a right to treatment of one's choice. But the framers didn't have the FDA (or some Democrats to deal with).

On the other hand, legislative and board efforts have been relatively successful. Many states now have some kind of health care freedom statute, or provide ACM doctors with some form of protection from prosecution merely because unconventional treatments are used. And let's not forget DSHEA. So I think continued legislative recognition of these rights is the way to go.

**AD: Do you see any major battles in the future?**

**RJ:** Codex and continued attacks on DSHEA [the Dietary Supplement and Health Education Act] would be high on my list.

**AD: That's an issue I've written about here, and so have others.‡ There is quite a spectrum of opinion about what impact Codex Alimentarius will have upon domestic access to natural remedies. What is your sense?**

**RJ:** Well, it's certainly bad news for Europeans and I think their health will suffer as a direct result of Codex. The whole premise of the new Codex supplement guidelines is based on a very dubious premise, namely that most people can obtain all their nutritional needs and maintain optimum health through the normal food supply. I think that flies in the face what we've learned through cutting-edge nutrition research.

But for us, in America, I don't think Codex will have a direct adverse impact. I know some believe that challenges in world trade courts will force changes in U.S. laws, but I don't see that. What I do see, however, is that certain factions in Congress, with the FDA's help behind the scenes, will use Codex to undercut DSHEA under the guise of good science policy and conformity or harmonization of U.S. laws to internationally accepted CODEX standards. And that worries me.

But without the internal attack on DSHEA, I don't think the external threat of CODEX could succeed. So it seems to me that our clarion call should be to protect DSHEA from the factions that are trying to eviscerate it.

**AD: Last question for you: Who are your heroes in the ACM field, and who is out there now leading the charge?**

**RJ:** Good question. Well, there are a lot of dedicated people out there helping patients. Of course I admire Burzynski's courage and Revici's tenacity. There's a young physician in North Carolina, Rashid Buttar, who is doing some innovative work with autism, and who is trying to change the shape of medicine, and I'm going to help him try to do it. There are many other pioneers out there who deserve recognition and/or who have developed promising therapies and approaches to illness.

But I have to say that where we are as a civilization, healthwise and taking into consideration science and public policy, I think the most important people in our community right now, and the people who can have the greatest impact in improving the population's general health and well being are the folks who deliver clinical nutrition services: that is, the certified clinical nutritionists, the C.N.s, C.N.S.s, clinically oriented dieticians, the many chiropractors who provide nutritional support services, and M.D.s who focus on nutritional issues.

**AD: I hadn't expected that answer. Why so?**

**RJ:** Because we are now at the end of the beginning stage of a possible major paradigm shift in health care. We've moving from curing diseases to prevention, from drugs, to the use of foods and supplements to prevent or lessen the chance for a disease process to take hold.

The shift started with people like Samuel Epstein, who has advocated cancer prevention through lifestyle modification, as a societal alternative to cancer treatment. Nathan Pritikin and Dean Ornish did the same thing for cardiovascular disease. Now, people like Patrick Quillen, Barry Sears, Joe Mercola, and many others have taken up the mantel and are forceful advocates for the power of foodstuffs to treat and prevent disease, and to establish a higher degree of wellness.

But it is the "retail" deliverers of nutritional services who are on the front lines of this paradigm shift. And that's because, unlike a paradigm shift in physics or chemistry, this shift involves the whole population.

This new paradigm will have to embrace and bring along the consumers, in part because the competing health care paradigms impact and are affected by public policy, which in turn involves governmental processes. And governmental processes, usually, hopefully, and eventually succumb to public will. Without the thousands of nutrition-oriented practitioners delivering their message, retail, patient by patient, client by client, there's very little chance that the shift will occur. But with them, there is an excellent chance it will happen. So I think these folks are the unsung heroes, and upon whose shoulders the health and wellness of society rests. And they need all of our support.

**AD: You have given us all much to think about. Thank you very much for sharing your thoughts.**

My pleasure. □

†United States v. Rutherford, 442 U.S. 544, 49th S. Ct. 2470, 61 L. Ed. 2nd 68 (1979).

‡*EDITOR'S NOTE:* See in *Alternative & Complementary Therapies*: Dumoff A. Legal matters: Decoding the Codex threat: Are limits on access to dietary supplements looming? 2004;10:343–349; Laibow RE, Dean KL. Special report/op ed: Codex Commission adopts vitamin and mineral guidelines. Discordant reactions greet harmonization efforts. 2005;11:169–172; Laibow RE. Op-ed: "Nutraceuticide and Codex Alimentarius. The death of nutritional medicine. 2005;11:223–229.

**Alan Dumoff, J.D., M.S.W.**, is an attorney practicing in Rockville, Maryland, specializing since 1988 in the legal issues regarding the delivery of ACM care. He can be reached at alandlmc@aol.com