BIO-TECH FRAUD:  
REALITY OR FANTASY?*

James Sheehan**

SYMPOSIUM ADDRESS

I'm an assistant U.S. Attorney and they require us to do various caveats before we do these presentations. I speak for myself and not everything I say is cogent, well reasoned, and thoughtful. Naturally, these are my own ideas and not the official policy of the Department of Justice. Second thing I want to tell you is if you look at your handout, you will see a telephone number that is there to assist concerned citizens who want to let their government know about significant issues that affect our lives. And also if you want to blow the whistle, that number will work just as well.

I want to be candid up front. I do not pretend to be an expert in biotechnology. I'm an expert in fraud. And if you've ever sat around with a bunch of lawyers, not something I recommend, the standard joke about litigators or trial lawyers is that their minds are like bathtubs. You put the stopper in, you fill it up to the top, you use it for whatever you're going to use it and you empty it again. And the idea is that once they empty it, that all that knowledge is gone. But that isn't really what happens.

So what I want to talk to you today about is applying some of the issues that we have learned in the fraud area to the unique and

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developing area of biotechnology. And this presentation is particularly timely. I can't discuss cases that are currently being investigated, obviously, but the amount of public attention this has gotten and the lessons that we've learned from prior fraud areas make it appropriate to take a close look at biotechnology at this moment in time.

One of the things that we have to do is to say well, what is going to be the impact if we get involved in investigating a new area? And we've learned to think about this impact from two perspectives; one is, what's the right thing to do? What kinds of things are appropriate for the inevitable disruption that fraud investigation and prosecution causes? What kind of things do we do in doing the right thing? And we've learned to think about this, particularly the right thing? And when we go back to Congress, or we go back to the public and say, “Support us on this.” The issue is, are we doing the right thing?

I want to start off today with talking about how I see biotechnology changing the world in the next five or ten years and the kinds of things we don't want to interfere with, because one of the kinds of things that fraud prosecutions can do is freeze an industry or freeze things that fraud prosecutions can do is freeze an industry or freeze things that are in its stage of development when there are great things an activity in its stage of development when there are great things an activity in its stage of development when there are great things they can do in the future. If you stop an organization with a lot of the creativity and energy and creative people and energetic people and require them to memorize a series of rules and to watch a videotape telling them exactly how to behave, then there is a risk that the rule people destroy the energy and creativity of the industry. And I think as investigators and as prosecuters, we have to be aware of that is a potential risk.

So I want to start off with the kinds of things that I see are the good things about the biotechnology industry. And I'm going to limit myself to the biotechnology which is related to health care. We can talk about crops, we can talk about various kinds of foods, but I'm going to limit myself to biotechnology which is related to health care. This includes the substances that are produced in the human body to fight infections and disease or do diagnostic work. This also includes the use of biotechnology devices in order to produce drugs and other things.

Examples of the kind of biotechnology we're talking about: the old stuff like eopogen that's been around for a long time, various drugs for ADHD, and diagnostic services. And I think the diagnostic piece is especially important, because this appears to be where the industry is headed. There is an interaction between the issue of drugs and the issue of the diagnostic tools used to make the drugs work.

Why is that significant? I use the analogy of a health club. When I first started going to health clubs a while back, if you wanted to run indoors they had a twenty-six lap track. It was banked and you would run around in circles. There was a big clock, and if you started exactly when the second hand was at the twelve, you could time yourself each time you passed within about five seconds. Well what's happened today? People who go to the health club and want to run now get on a treadmill. And every minute, every second, you can tell how many miles you've run, you can tell the average pace that you've kept, you can tell how many calories you've burned and about four or five other digital read outs that will tell you what's going on. All this, for an activity where what does it really matter?

I've also had a chance to watch my father, who's a diabetic, and has several other medical problems, monitor his condition on a daily basis to find out exactly what's going on, whether the various medications he's taking are working and what his blood sugar level is. I'd suggest to you that this model of the diabetic managing in his own disease is to a large degree the model we're going to see in the future. People want to know whether the things they are taking are working. Well, most of you think that is what doctors are supposed to do, but here's the difficulty. Most drugs don't work well for about half the patients, for whom they're prescribed. There are a variety of reasons for that: just think of all the things that affect the effectiveness of drugs. You take grapefruit juice in the morning with the pill that you take, it changes the metabolism of the drug. If you are a regular consumer of large quantities of alcohol or even medium size quantities of alcohol, it changes the way the drug is used. If you have compromised kidney or liver function, it changes the way the drug is used. If you have a genetic problem of various types, it changes the way the drug is used and what kind of side effects it will have. The research suggests that over half the drug dosages are not appropriate for the patients for whom they are prescribed. These things are bad, but don't we still have clinicians whose function is to make sure that the drug works? The information the clinician has today about whether the drug works is relatively limited. If you have a doctor who is really dedicated, he or she may run blood tests once a month when the patient walks in the office or once every two weeks to see how the drug is being used and what effects it is having. In reality, most doctors use standard
doses of standard drugs and then modify them based upon the patient's reaction. And their ability to monitor the patient's reaction is not that great.

So what causes these two things? What results in half the drug dosage not being appropriate for the patients for whom they're prescribed, and most drugs not working well for about half the patients?

Here's what happens. You have an entire industry at the moment that is designed to address those problems in what I will call an old industrial way. Henry Ford said you can have any car you want as long as it's black; to some degree the drug manufacturer industry at the present time is at the same level. With Henry Ford's black cars, or even Soviet cars about 10 years ago, people were so desperate to have them that they really don't care about the minor things that didn't work on them. The final model is IBM. Why would you want to have personal computers when you don't make as much money on them? Let's stay with the standard big size computers that banks and other people will buy. All the advantages that exist with what I will call industrialized medicine accrue to a variety of players in the industry.

Let's start off with standardized research and development. Ford learned how to make cars on the assembly line incredibly efficient, paid people well, got its product out the door. If we look at the drug development industry, we know what the research is supposed to look like, double blind studies, large populations with standard monitoring for side effects and standard reporting techniques.

Mass production is another advantage. Assume we set up a factory in Puerto Rico; we can crank out hundreds of thousands of pills every day.

Mass marketing. If we have a product, we know exactly what the parameters of the product are, we market it to everybody. You turn your television set on, you see Prilosec or you see Claritin or you see some other drug. It is marketed to the entire world or at least the entire United States population who might take it, and not to anyone in particular. It is not really targeted. It is just not that difficult to design advertising which is going to go to a large population.

The next advantage is mass regulation. And why is mass regulation an opportunity? Well, here's what happens today in looking at drugs. When I am the FDA, I have policies that I've had in place for at least the past ten years, and in many cases, the past forty years that tell me what the studies are supposed to look like and what kind of side effects are tolerable. I have the standard committee approach for drugs that are going to deal with large scale populations. This is a lot easier than having to get the details of what works and what doesn't at an individual patient level.

The next advantage is standard dosing for patients applied by physicians. What is the advantage of that? The doctor doesn't have to think about fifteen variables for each patient. Because they know if they are going to order, for example, a standard SSRI antidepressant, they order the standard fifteen milligram pill or the standard thirty milligram pill, then adjust if the patient has significant side effects or it doesn't work. It's a lot easier for doctors to do that than it is to sit there and say, "Okay, well, what are the lab values, what's the patient's weight, what do we know about fifteen other things that are happening in the patient's body."

The final advantage with standard dosing is minimal follow-up costs. This is just something that happens with these drugs. You don't spend a fortune on laboratory tests and visits to specialists and so forth; this is simply the standard regimen and we know how it is going to work.

Who gets the benefits of these standardization processes? Well, drug companies for one, because it's a lot easier to market a large drug to a universal population than to design them specifically for each individual. Insurance companies get the benefits as well, because a better drug regimen that required a lot of monitoring and a lot of support and products would cost insurers a fortune, yet their customers would demand it. Physicians receive benefits to a limited extent because they have standard dosing and don't have to think about these medication issues and government agencies. So that's the regime we have now, which I will call the pre-biotech regimen.

What are the disadvantages of this approach? 60,000 deaths and 1.6 million hospital admissions a year for drugs which are prescribed according to the labeling or are unintentional mistakes. And you may say well, those are numbers from activists who really don't understand the real picture, but those are numbers from the PBRMA—the trade association for the innovator pharmaceutical companies: 1.6 million hospital admissions, 60,000 deaths.

The second disadvantage is that there are millions of unreported adverse effects. All the research that I have seen suggests that no more than ten percent of adverse effects from patients are reported in any way. First, the effect has to be reported to the physician; probably a quarter to a third of all adverse effects are reported
to the physician. Then, the effects have to be reported by the physi-
cian to someone else, and the number drops way down.

The third problem is the failure of compliance with drug regi-
ments. This is an issue because when patients have side effects from
drugs because it’s a wrong dose or it’s inappropriate for them,
what’s their natural reaction? They stop taking the drug. Especially
when it’s a chronic long term condition that’s not going to go away,
but doesn’t kill you right away: individuals with high blood pres-
sure, high cholesterol, even those taking antidepressants face that
kind of problem. Patients’ uncertainty is another problem because
the patient doesn’t know if the drug is going to work.

Another problem is industrialized medicine’s approach to
drug’s with significant potential benefits but major risks to some
patients. If we are designing a product for the population as a whole
or a significant part of it, some percent of the population is going to
have adverse effects because of their genetic makeup or other issues.
If the product is targeted broadly for the mass population, you can’t
easily identify who in the target population is going to have these
effects. You may have to take the drug off the market or make it
more difficult to get, through black box warnings to physicians or
pharmacists.

The final disadvantage is that drug regimens are seldom ad-
justed based on empirical data. You look at pharmaceutical data on
the patient level, and you say, “What actually happened?” What in-
formation did the doctor have in front of himself or herself to make
formation. The answer is, remarkably little. If
the decision about this patient? The answer is, remarkably little. If
you look at what the medicine labeling says, it says the physician
should consider monitoring in follow-up studies thirty days, sixty
days, ninety days out. How often does that actually happen? How
often does the doctor think of it? How often does the doctor do it?
How often does the patient show up to have his arm stuck with a
needle to have blood drawn? How often does the results get to the
physician? Look at these questions in the context of shortening pa-

tient visits and less of monitoring patients, and this becomes a sig-
ificant issue.

There are techniques to deal with these problems, many of
which are biotechnology techniques already used in certain places.
However, these techniques threaten to be so disruptive to the busi-
ness of the big drug companies that many of them are resisting its
widespread use. This is not me talking, this is the Wall Street Jour-

nal, which is not exactly a wildly radical publication. And the issue
they raise is, what’s going on? Why is it that these available tech-
niques have not happened? Drug manufactures in the past have sort
of tried to take a run at these issues to custom design medicine but
they have backed off. Smith Klein in the mid 90s had also an-
ounced its strategic approach, which was going to try to incorpo-
rate the lab side and the monitoring side to determine whether the
drugs could be customized drugs. Eventually, everyone gave up
since it wasn’t going to make any money in the short term. The
other problem was that the kind of people who are successful in
marketing an organization that markets mass drugs and who will
advance to management are very different from the people who are
going to be successful in marketing the customized programs.

So my vision? Biotechnology gives us the opportunity to cus-
tomize drug regimens; to customize treatments in a way we’ve
never done before by mixing both the biotechnology product and
the monitoring system. Imagine diabetes disease management times
ten in terms of being able to tell on an hour-by-hour, minute-by-
minute basis what’s really going on with the effects of those prod-
ucts. Patients will want it if it exists, and use it if it is made availa-
ble—to give them greater control over their diseases and lives.

So you say, I came here for a speech on fraud, what’s all this
got to do with it? There are two kinds of laws. The first kind of law
says, for example, “Thou shall not smoke in the first car on the
train.” We know what the rule is; it’s an arbitrary rule. We know
pretty clearly what it says. That is, if you get in the first car, do not
smoke; other cars, you may. The idea is that it’s positive law; it says
that you must do this, you can’t do that. Unfortunately or fortu-
nately, in both drugs and biotech, because the regulatory scheme
seems so controlling, the natural reaction of those people who focus
on those prescriptions and proscriptions is that you must do this,
you can’t do that. When we talk about fraud, we’re talking about a
very different kind of law. I don’t know if you saw in the Olympics,
there were two cross country skiers who were disqualified after
they got their gold medals. Why were they disqualified? Because
they took the next generation epon, the anti-anemia drug to assist
them in increasing their red blood cells and their ability to process
oxygen. Now here’s the interesting thing about that disqualification:
there is no positive rule forbidding this new kind of epon because
it’s so new the Olympics committee, being 2000 years old, has not
rewritten the rules to cover it. Well, these athletes are out of it any-
way. Why? Because they violated the spirit of the rules prohibiting
the taking of artificial substances. It will be interesting to see what
the litigation about that is like.
What's breach of trust in there for? Deception is pretty straightforward: you lie or you try to create a false impression. But what is breach of trust? Breach of trust is a broad and important category because it recognizes that there are certain kinds of relationships between people that are so apparently unfair and unequal that we're going to impose a higher standard on the more powerful and knowledgeable person. If you go to a used car lot out on I-10 somewhere forty miles west of where Houston starts, and you see a used car lot and you actually get out of your car and talk to the sales people in the used car lot, what is your expectation about what those people are going to tell you? You have a filter, because you don't assume that they're going to tell you this car was in an accident, unless it's required by law. You don't assume they're going to say this car was owned by the little old lady who drove to church every Sunday and had also been cag racing every Saturday night. You don't expect that to happen.

But now suppose you go to your doctor's office and your doctor says, "I may have some difficult news for you, my concern is that you may have cancer and there are these five tests that I want you to take." Is it possible, objectively, that he thinks or she thinks you may have cancer? It's possible. Are those five tests necessary and appropriate? Well, the breach of trust standard says the doctor has to believe in his or her mind, in good faith, that this is the right treatment for you. He should not be ordering these tests because he's getting money from the companies that provide the tests. Even though he never says to you, "I don't own the companies," even though he does not say, "I'm not getting any payment for referring you," you are dependent upon that physician's judgment. You have a professional relationship with him, in which he has to make the decision in your best interests. So even though there's no lie, you can still have fraud.

So how do we look for ethical content? What should define a high trust relationship such that breach of trust is a crime? What should be the standards for deception? What you find if you look at the law in the long run is that fraud tends to follow ethics. I have a quote from an immunologist at NYU who, talking about the specific drugs versus more general drugs, says "This is an ethical issue. We don't want to put patients on drugs that aren't going to work. In complicated diseases it takes months before you know whether the drug is helping the patient. Think of the suffering." And here is a quote from the chairman of Genaiance talking about the drug companies not being able to discover limitations of their.
drugs. “Glaxo has filed for patents on genetics tests for the effectiveness of its asthma drug, but Glaxo has no intention of creating the tests itself or letting anyone else do it.” My favorite quote is from the head of genetics at Glaxo: “They can go screw with someone else’s drugs.” The theory with mass production is that we want to get this product out but we don’t want needed and helpful information to be available to patients or their physicians.

So I’ve talked about good faith and fair dealing as understood in the community involving deception and breach of trust. What other kinds of factors are going to turn biotech issues into fraud issues? I’m going to walk through those.

If you look at the old days, fraud in the hospital context usually revolved around billing. What kinds of claims are submitted for services? What kind of third-party payer is paying the money? What kind of benefit is the organization getting? These cases have some appeal because people got money they were not entitled to. But I’d suggest to you that the bigger issues going forward are not the issues of billing for services not rendered; the bigger issues are what is happening to the patients.

This area has people nervous about how different it is from the typical hospital fraud context. The law has a couple of boxes to put this new type of fraud into, one of which is reckless endangerment. This involves performing treatments on people that you have no confidence will work, or may even put them at risk. Medical necessity is another way to deal with this new fraud. This involves asking whether the treatment is actually good for the patient when you treat them. Worthless services is a third way to cope with frauds such as misleading the patient about efficacy or risk.

When you have new products or you’re signing patients up for trials, do you tell them what they’re likely to get into? Patient experimentation without disclosure and false representations about benefits, likely benefits of the protocol, or known alternative treatments can be part of a scheme to defraud. The primary focus in all these areas is on the patient, not the government, not the third-party insurer, not some plan or fund. What is happening to the patient? I think if you look at this area, you see products that have a tremendous amount of trust involved in them. When we talk trust, we are dealing with the flip side, the breach of trust standard. So what kind of issues have we already seen in the biotechnology area, at least according to published reports in the press?

First, we have seen the potential corruption of provider judgment by payments. Every biotech company that I know has a bunch of people with degrees from distinguished institutions on their board of scientific advisors and usually on the board of directors as well. If you look at the research, it’s often being undertaken by either institutions or individuals who have a stock interest or a royalty interest in the product being developed. Some places forbid that, like Harvard, but a lot of places do not. Those that do forbid this interest conflict sometimes will say, “Well, we forbid it for individuals, but we don’t forbid it for the institution.” But here’s the problem with that. If you have somebody on your faculty who’s generating $10 million in royalties every year and knows that his position with the institution depends on bringing that money every year, how is that likely to affect his judgment in treating patients and deciding who is going to sign up for the study and who isn’t?

Clinical research fraud is another problem area. If I have an economic interest in a particular product, what are my incentives to think about judging the research in one direction or another? Or exposing patients to harm? If you look at the local papers in Philadelphia, and I’m sure this happens here too, you can see the research marketing that is occurring. We call Philadelphia the guinea pig city because there are so many studies that you can sign up for virtually anything. What kind of stuff is going on out there? What are the patients signing up for and what are they doing? And what do the researchers tell the patients about the situation?

Two other areas that I think are significant in fraud issues are securities fraud and FDA false statements and failure to report. The securities fraud is fairly obvious. I’ve followed a biotech stock since the early ’80s, and I think I’m on the fourth cycle now. It’s one of these things where you can say at various times, I could have paid for two years of college for my son and now I can buy half of a Yugo. And you look at the press releases over time for these biotechnology companies and what happens to the price—it’s an interesting pattern. I want to believe that optimistic statements are just good faith judgments about future events that are not actionable.

The FDA rules governing false statements and failure to report is another area for concern. The failure to report significant adverse events to medicine must be one of the most ignored statutes in the country. My prediction is, in light of the cases that have come out recently, that this failure to report adverse effects is going to be a growing issue.

But I’m going to flip now to the issue of clinical trials and research. Now what I’m going to show you is a 60 Minutes piece from about ten months ago. This piece is significant in the biotech world
because it looks at research and what goes on in the relationship between patients, physicians and the drug manufacturers. When you watch this tape, I’d like you to think about three things: one, what is the fraud violation? What actually is going on? What’s the breach of good faith and fair dealing? Two, who’s the victim? And three, where do the cases we get come from? How do we get them? And what kind of moral compromises do we have to make in order to get those cases?

(Videotape was shown.)

Now, if we look at that video, the first question is, who is the victim? How many people say Tom Parham, the patient who required a pacemaker because of adverse effects from the study drugs? How many people would say the drug manufacturers, who paid for what turned out to be bogus research? That case was prosecuted several years ago, and the drug manufacturers were described in the indictment as the victim because they were paying the money. If that case was prosecuted today, I don’t know that the case money. What he says is, “My doctor” waives me down the hall, what are you going to do? I trusted my physician.” He has been deprived of his doctor’s “loyal and faithful service” through his breach of trust. Here’s the result of mixing of the treatment aspect and the research aspect and not disclosing possible dangers to the patient – the patient almost died.

Now, let’s talk about Susan Lester, the nurse described in the tape as a whistle blower. Let’s think about her for a second. What was actually doing? She was the clinical coordinator for these studies, a licensed registered nurse, and what was she doing? Studies. She’s helping the doctor obtain blood and urine samples from the patients. She presumably knew the doctor was cooking other people on staff. She presumably knew the doctor was cooking up the X-rays and cooking up the bacteria studies, she knew about the change in the records in the hospital. What did she do with that?

You can imagine also that if this case were to go to trial, what

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the office. He certified what Susan Lester told him to certify, he couldn’t have engaged in the acts that are described here. And you can tell that there was a problem with this type of argument because the doctor pled guilty to a conspiracy charge and was given only a fifteen month prison term for this size fraud.”

So what do we learn from this? Well, number one is how the government finds out that these things are happening – typically, we don’t. If you look at what you saw on the videotape, how many inspections had they done since this inspection office started? Two. Do you know how many clinical studies there are? You can pick up any newspaper and find ten ads for clinical studies in there. You can go on the internet and look for research trial studies and pick one out of the thousands that are on the lists.

So what happens in the industry when there is no enforcement of these standards? What’s likely to happen? There’s a lot of money made on the back end if these products are approved and put on the market. The answer is the industry polices itself to some degree, perhaps doesn’t police itself at all. Now this problem so far has been primarily in the academic medical centers, except for doctor Feddis and a few others. If you read the newspapers, you can see the Jesse Gelsinger case, a case at Hopkins in which one of their employees died, the case at the Hutchinson Cancer Center out in Seattle, the lead paint studies in Baltimore. I would suggest to you there is probably much greater outside the academic setting because in these cases there are a lot of people that have a responsibility to look at these things and see what’s going on, such as those individuals on IRBs. Some of them are sort of stubborn and unwilling to go along just to go along, which is part of how we find these things out. Somebody blows the whistle. Somebody says this happened at such and such an institution and blows the whistle.

And the second part of locating these problems is, suppose something bad happens at Hopkins or Penn, and you’re a plaintiff’s lawyer. You see that case number one is a Hopkins or Penn defendant; case number two is Dr. Feddis who is about to go to jail and have all his money taken to defend himself. Who becomes the defendant in those cases; which case do you pick? You don’t take Dr. Feddis because you’re never going to see any dollars; instead, you take the cases which are the large institutions. I would suggest to you that what is happening is that the visible tip of the iceberg are the large institutional problems and that much more is going on in some physician offices with contract research organizations “overseeing” them.
Now, suppose that you’re running a contract research organi-
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When I look at this case with Dr. Feddis, I say there are ten companies involved and I want to find out what they knew, when they knew it, what questions they asked, what kind of inspection they did, and what they did when they found out there were problems, because they could be a victim, they could be a witness, or they could be a target depending on where they fall in that spectrum. A new product development man-
ager is under tremendous pressure to get the product approved and out the door. So what does an appropriate compliance program look like in this field? What should you do with these kinds of re-
search issues?

If you ever have to try one of these cases, it is not only the juries who may have difficulty in understanding the science. I had a biotechnology case about two years ago, and we had an injunction action. The doctor in charge had a National Institute of Health re-
search grant and we were arguing about whether he had retaliated against a whistle blower. I had to explain some of the science to the judge and then my opponent had to get up and explain the science from their perspective. The Ph.D. M.D. that was in charge of the pro-
ject after we did our thing said, “It’s clear to me that neither of you,” pointing to me and to his high-priced private counsel, “have a clue what we’re doing here.” Maybe true, but this was also the kind of person I’d like to call as a witness in opposition because he’s not the kind of guy that’s going to endear himself to the jury or to a judge. Juries don’t understand this intricate science easily, and for the most part lawyers don’t either. So juries try to grab on to some piece of the science that makes sense to them. What makes sense in this 60 Minutes video, from our common experience? Blood and urine taken from employees, ordering the X-rays and reading them him-
self, ordering the bacteria, and falsifying medical records. These are all things that we can grasp.

If you look at the fraud patterns in every industry, they start out by people generally playing by the rules. Then some people get

very aggressive and the people who are not aggressive start to lose

out. Then what happens is people come to the legal departments or the compliance officer and say, “Look, everybody else in this indus-
try is doing this; there’s no enforcement, what’s the big deal? Let us do it.” They are all working inside the industry and are not seeing what the outside world is likely to see. Then we find a few cases and we, the government, learn how to investigate and try them. We fig-
ure out how to put a case together based on an understanding of the business and its culture and then we teach each other.
We had a training program for advanced lawyers in South Carolina last fall on how the research process works. So when we know what questions to ask the whistle blowers when they come in and tell us things, then we have two or three cases. Then we go around to presentations like this and talk about them to our colleagues. Once they realize they can do this as well, they start to listen for problems and the cases start to come. So if you are in this business or are advising people in this business, what kind of advice can you give? I said before that the issue is focusing on the patients. That’s what the jury is going to focus on, that what the fraud statutes are basically designed to protect, the victims of the fraud, so I have a couple of suggestions in my outline on advice to give people in this business.

Number one, meaningful and full disclosure to patients. This is research, not treatment. Our primary responsibility is to manage the study, to obtain accurate information about the study medication; you should consult your own doctor for advice if you have any concerns. I’ve looked at a lot of consent forms and later in that video, Margin Angel says that they’re written by lawyers for law firms, so instead of looking at the consent forms, what I would look for is how you are conducting the study and what you tell the patients. I don’t mean to tell the patients, forget the patient word. What do you tell the research subjects? When I ride the bus or public transit in Philadelphia, I see signs posted for the general population that say, “Are you depressed? You can be expected to participate in this study.” They want you to stop taking the antidepressant you’re taking, take experimental medication or a placebo and be poked and prodded by people who are not there to treat you. Does that sound like deception? That sounds like deception to me.

Second, there is a risk of harm to you from participation in the study, the drug or devises itself, and from the failure to use alternative treatments. I will benefit financially from this research and from your participation. This is pretty important, because when you saw Tom Parham here say, “I didn’t realize at the time when he was,” really waltzing me down the hall that he’s going to get $1600, it really upset him. And one thing about television, they’re able to pick out what is really the hundred words out of thousands in a discussion that really catch people’s attention. If I had a witness like Tom Parham for the jury, he would be very, very persuasive. Although there are a bunch of regulations, FDA, Helsinki Protocol, whatever, none of these are regulations. NIH, Helsinki Protocol, whatever, none of these are regulations. FDA, NIH, Helsinki Protocol, whatever, none of these are regulations. FDA, NIH, Helsinki Protocol, whatever, none of these are regulations. FDA, NIH, Helsinki Protocol, whatever, none of these are regulations. FDA, NIH, Helsinki Protocol, whatever, none of these are regulations.
the tobacco company said in public was different from the information they had in their organizations.

With public relations and certain kinds of sales promotions, you never put out everything you know about what you have, you put out the things that are most favorable to your position. Lawyers might do that too. Not government lawyers, of course. So the issue is at what stage does the controlling of information that comes out of of studies in research become fraud and deception? The short answer is, we don’t know. We won’t know until the bad event happens, until the Hopkins employee or Jesse Gelsinger dies or the kids who live in the Baltimore lead paint study houses who suffer significant losses in their intellectual abilities or the cancer patient at Hutchinson start to die off. You won’t know when one of these studies goes bad, nor when one of these research efforts go bad. So the compliance effort has to be focused on when that event occurs.

What can you say about the organization? What can you say about the product? What can you say about the quality of the research? And what can you say about willingness to report what the results were? These are all very tough issues because not only within companies, but also within academic institutions and contact research organizations, the inclination is to accentuate the positive. It also requires a fairly strong internal organization to address these issues and make sure that the information comes out in a way that’s fair and that you can defend afterwards.