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7-1-1999

Fraud and Abuse

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Recommended Citation

Mark Langdon, Eric S. Tower, and Eric Roth, Fraud and Abuse, 7 U. Miami Bus. L. Rev. 438 (1999) $A vailable\ at:\ http://repository.law.miami.edu/umblr/vol7/iss3/6$

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V. FRAUD AND ABUSE

TIM RAVICH: The next segment is going to deal with fraud and abuse. [This panel is occupied by] two gentlemen from out of town and a local legal practitioner. I will start with the gentleman in the middle.

MARK LANGDON works for the law firm Arent Fox Kintner Plotkin & Kahn in Washington, D.C. as an associate in the health care group. Mr. Langdon's practice has focused primarily on the representation of health care providers such as nursing homes, health agencies, and physicians on a wide range of issues including fraud and abuse counseling, federal and state health care fraud investigations, federal and state regulatory compliance, corporate practice of medicine, Medicare and Medicaid reimbursement. Mr. Langdon regularly advises clients on structuring provider joint ventures, integrated delivery systems, and other health care business arrangements to comply with federal and state fraud and abuse laws. Mr. Langdon has participated in negotiations on behalf of providers for the Office of the Inspector General, the Health Care Financing Administration and various state Medicaid fraud control units. The gentleman to Mark's immediate left is Eric Tower.

ERIC TOWER works for Mintz, Levin Cohn Ferris Glovsky & Popeo, P.C. in Washington, D.C. He is an associate in their healthcare law section. His practice encompasses a wide variety of transactional and regulatory matters, including mergers and acquisitions, joint ventures, contracting, reimbursements, certificate of need, licensure, managed care, federal and state provider regulation, fraud, and abuse. Eric has worked exclusively with health care law since 1992. He has represented a wide variety of health care providers and manufacturers. Eric earned his B.A. with honors from Northwestern University, his J.D., cum laude from the University of Wisconsin and his LL.M. in health law from the Loyola University Chicago School of Law.

Next, ERIC ROTH. Mr. Roth is a graduate of the Georgetown University Law Center. Mr. Roth is an associate in the Miami office of White & Case. Mr. Roth is a litigator whose areas of practice include general commercial litigation, bankruptcy litigation, admiralty litigation in both the state and federal courts. [Mr. Roth] has practiced before administrative agencies and [engaged in] appellate work in the federal and state courts including the Florida Supreme Court.

With that, I will turn [it] over to you. Mark.

MARK LANGDON: O.K. Thanks. First I'd like to thank Tim Ravich and the members of the *University of Miami Business Law Review* for flying us down here...

What I'm going to talk about... I am going to present a general overview of federal health care fraud and abuse. And I'm going to go over some of the statutes that impact a number of providers and physicians. Eric [Tower], on my left, will be talking about the anti-kickback statute in some detail. And Eric [Roth], on my right, will be talking about compliance plans as he has some has experience with investigations. I have some hand outs, I hope people grab those . . .

First of all I want to talk about the general health care enforcement environment today. As many of you know from reading articles in the newspaper about Columbia/HCA and various other investigations have been going on. — it's a very aggressive health care enforcement environment today. Janet Reno, several years ago, declared health care fraud to be the number two initiative, just behind violent crimes, to the Department of Justice. And also, as I indicated in the outline, the General Accounting Offices estimate that as much as \$100 billion is being lost every year to health care fraud and abuse. That's a pretty high sum, so providers have to be keenly aware of all the statutes that come into play when they are trying to structure arrangements. Another thing is there have been a number of very aggressive prosecutors and assistant U.S. district attorneys who have been trying to advance some very novel theories in going after physicians and other providers. That's something we also need to be concerned about. And as I think Eric [Roth] may talk about . . . in some detail later. There is a recent case in Kansas City whereby some health care attorneys were indicted and these were well-respected fraud attorneys. And they were indicted. Basically, it was believed they were conspiring to violate the anti-kickback statute because they were giving advice, allegedly to help their clients try to structure arrangements that were in violation of the law. The case was recently dismissed. That just shows how it's a very heightened and very aggressive environment today.

Basically, in my opinion, there are three main weapons the government can use to go after healthcare providers. First, one is the Federal Civil False Claims Act;² second is the Federal Anti-Kickback Statute;³ and the last one is the Stark law, it's called Federal Physician Self-Referral Law, which was named after [California Representative] Pete Stark and it's called the Stark law.⁴

Let me go through the False Claims Act first and if anybody has any questions along the way just holler, stop and I will try to answer those. The

United States v. Anderson, No. 98-20030-01, 1999 U.S. Dist. LEXIS 1730, (D. Kan. Jan. 8, 1999).

² 31 U.S.C. § 3729 (1999).

³ 42 U.S.C. § 1320a-7(b) (1999).

⁴ 42 U.S.C. § 1395nn (1999).

False Claims Act — mainly because of the enormous penalties that can be imposed on providers is probably the government's most powerful weapon in this fight against fraud and abuse. Basically what it provides is that it is a civil offense to present a false claim to the government or to cause a false claim to be presented to the government and you have to knowingly present it to the government and it has to be false or fraudulent. What that means basically is that there is no specific intent standard that's required; it's not a criminal statute. The government needs to show there was actual knowledge or deliberate ignorance of the truth or falsity of the information that was presented within the claim. The main examples of the application of the False Claims Act are when a doctor submits a bill to the Medicare program for services that either were never provided or provided but weren't medically necessary. Another example is if a doctor claims a reimbursement code on the claim form but it was actually a higher code than what the service should have been coded into. The main penalties that can be imposed upon providers for violation of this act are treble the actual damages. So, in other words, if the government suffered \$10,000, you would multiply by three — that can be an enormous sum — and then \$5,000 to \$10,000 per claim that's submitted to the government. In other words, every time a physician submits a claim to the government, the physician submits ten claims a month or a hundred — you would multiply that by \$10,000, plus three times the actual damage, you could get some enormous sums that can be levied against the providers. And because of this there is an obvious incentive for providers instead of going [...] to litigate these cases, there is an incentive to settle with the government. And also there is a provision that was enacted to the 1986 amendments to the False Claims Act which allowed qui tam relaters to basically bring an action in the name of the government as well as in the name of himself against a provider and lots of times these qui tam relaters work for the provider, like work for the hospital and they somehow uncovered that the hospital may have been doing something fraudulently, like billing for services that weren't provided. And that person can go to the government, disclose what he/she knows and they can get up to 30% of the funds that are eventually awarded. There's obviously a huge incentive to go to become a relater, blow the whistle on the company and try and get a large sum of money back.

The second statute I'd like to talk about is the Federal Anti-Kickback Statute. It's a criminal statute which basically prohibits the offer or the receipt of any type of remuneration that is intended to induce the referral of patients whose services would be covered by a federal health care program and also, which is intended to induce the purchase, order or lease of any items or services that are reimbursable by a federal health insurance program. Again, the penalties for this statute are very severe: five years imprisonment or \$25,000 fine — and one of the most important penalties are that you can be

excluded from all federal health insurance programs since a number of nursing homes and home-health agencies depend very heavily on getting money from Medicare and Medicaid. This could provide a huge incentive to make certain that the appropriate compliance measures are in place so that the other arrangements with the other providers are [in compliance with] the statute.

There are a number of what are called, safe harbors to this kick-back statute. If you're structuring a transaction and the transaction fully qualifies for a safe harbor — that means basically that you are guaranteed immunity from prosecution. ... Later there's been — some people say there's been a split in the government. The Department of Justice has indicated that even if an arrangement meets a safe harbor, they can, if they want to, try to look behind the safe harbor and say that in essence it was actually a sham transaction that was designed to meet a safe harbor, but in reality the parties are trying to make payments for referrals. So, it's very important to make certain that you can structure the transaction to fit into a safe harbor and make certain that you're continually monitoring the arrangement to make certain that the payments continue to fit within that safe harbor. What's very significant about the anti kick-back statute is that it's criminal, so even if you don't fall into a safe harbor, since it is an intent-based statute, the government has to prove intent. And basically that's a fact-and-circumstances type test that the government has to prove that payments were being made with a purpose to induce referrals.

Providers . . . have the option of trying to seek an advisory opinion from the government. Oftentimes hospitals want to run into relationships with physicians and they don't know whether the kick-back statute has been implicated or not. And a couple of years ago, the advisory opinion process was adopted and that means that providers can submit a request to the Office of the Inspector General at the Department of Health and Human Services and they can outline their proposed arrangement. And the Office of the Inspector General will, hopefully, give an opinion as to whether they think that transaction will implicate the statute or not. There are obviously a number of drawbacks with going forward with it request[ing] for an opinion because once you get the opinion, you're stuck with it. There's always a chance that the government might say "No." So, if you try to do it later on, you're obviously going to subject yourself to various penalties. That's basically the anti-kick back statute and as I mentioned. Eric [Tower] is probably going to go into a little more detail about its application.

The last statute I'd like to touch upon is ... this is a statute that I'm sure a number of physicians are familiar with — the Stark law. Basically, the amendments to the Stark law went into effect January 1st of 1995. To my knowledge, I'm not aware of any enforcement actions that have been taken by the federal government against hospitals or other physicians or other providers

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for violating the Stark law. But last year in January of 1998, proposed regulations were set forth by HCFA and those regulations will probably be finalized in another year or two, and once they are finalized I think we will see an increase in enforcement actions being taken against providers in violation of the statute.

Let me just run through the basics of the statute. The statute prohibits a physician who has a financial relationship with an entity from referring a Medicare, Medicaid patient to that entity for the furnishing of certain types of services unless that relationship qualifies for an exception. Again, the penalties are very severe. Up to \$15,000 for each service, forfeiture of any reimbursement of services that were provided based upon the unlawful referral and also potential exclusion for Medicare and Medicaid. And the basic policy objective behind both the Stark law and the anti kick-back statute is that the government feels that if a physician has a financial relationship with an entity, that will make the physician more likely to order unnecessary services from that entity instead of looking after the best interest of the patient. And there have been a number of government studies, one by the General Accounting Office several years ago and that is why these statutes needed to be adopted. One of the main differences between the Stark law and the anti kick-back statute is that as I mentioned, the anti kick-back statute is intent based, so therefore, the government needs to prove that there was an intent to violate the statute. Under the Stark law, intent is irrelevant. So whether the parties have good intentions or not, what matters is if you violate the statute and you do not meet an exception, then basically, — can be imposed, but as I mentioned, to date there aren't many enforcement actions taken.

And what I'd like to do now, is give you a real quick example of how, in my opinion, how absurd the application of the Stark law can become. We represent a lot of opthamologists and this example is actually on page 9 of the handout, it's number 3. Basically, if a Medicare patient receives cataract surgery, and then receives eye-glasses that are prescribed by an opthamologist after the surgery, Medicare covers eye-glasses only when they're furnished after cataract surgery, so this would obviously be a Medicare-covered service. Let's assume that the opthamologist owns an optical shop, which is very typical today. What would happen is that the opthamologist would perform the cataract surgery. The opthamologist would refer the patient downstairs in the optical shop for the glasses. Basically, this arrangement implicates the Stark law because we have a physician, the opthamologist who's referring a patient to an entity which is the optical shop, with which the opthamologist has a financial relationship with and the only applicable exception would be the "in-office ancillary services" exception. And what that means is that the opthamologist for another physician in his practice would have to directly supervise the furnishing of the glasses to that particular patient. That sounds very absurd because opticians are the ones that are licensed under state law to do this, but under a literal reading of the Stark law, the arrangement I just described — the opthamologist or the other physician did not directly supervise the furnishing of the glasses. So it's a violation of the Stark law. Now whether the opthamologist has to be present while all the glasses are furnished or whether he can be upstairs performing surgery, that's unclear right now, but, the fact that the opthamologist is not in the same building when this is being performed would constitute a violation of the Stark law and shows how far reaching this particular law can be.

Last, I just want to touch upon briefly on what I think are the key issues in the future with health care fraud and abuse. I think that with very aggressive prosecutors we are going to continue to see a very heightened enforcement environment. I think we'll see a number of qui tam relaters blow a whistle on their companies and try to get a chunk of the recovery. As I mentioned before, once the Stark law proposed regulations are finalized, I think we'll see the government start to target physicians and other providers, and I think we will also see an increase in enforcing in the managed care arena. As most of you know, under traditional Medicare fee-for-service service, the incentives are for over-utilization because basically the more services that you provide, the more you get paid. But under the managed care arena, it's the opposite, the incentives are for under-utilization and we have quality of care issues that are raised. I know the DOJ is currently undergoing a number of investigations with managed care companies in the country right now. One of the things they are targeting when the HMOs either enroll or disenroll people based upon their health status and that sometimes they'll conduct marketing campaigns, they'll call up Medicare patients and try to find out basically how sick they are, decide whether to sign them up based on that decision, and I think that's a violation of federal law, and I think we will see an increase in enforcement in that area as well. So that's a basic overview of fraud and abuse and think Eric [Tower] will go into more detail on the kickback statute.

ERIC TOWER: Mark [Langdon] . . . covered the basics. Basically with respect to the anti kick-back statutes, it's an extremely broad statute, but it's important to keep in mind that it basically covers every transaction that you can imagine. Any payments between professionals, any time you lease space, any time you lease equipment, any time a provider is getting a rebate or a discount, free goods, incentive payments between hospitals and physicians, any time you purchase an interest in a health care provider, there is a good chance that it could be implicated. If you're providing a bundle of goods and services to a health care provider and you're a manufacturer, you've potentially got an issue there. [...] And one thing that lately has been coming

up a little bit is hospitals providing courtesy services to physicians and a medical staff and that sort of thing. And again, that might, or might not fall within the statute. And [if] you're wondering why I'm saying "might or might not," that's because the statute itself is extremely vague. It doesn't really have definitions in the sense that we'd all like it, it doesn't define the concept of inducing referrals, for example. So there are two problems to the statute. There is a problem that prohibits remuneration in return for referrals. You guys would probably think of that as getting paid a bundle of cash in return for making a referral to someone. That's pretty clearly prohibited [...]. The other problem picks up remuneration intended to reduce referrals and that's where most people get into trouble, because anytime you've got a relationship, it's very hard to determine what the underlying purpose of that is.

Obviously, people want a relationship; it's beneficial to both parties and in the real world, people want to make money off it. Well, there are some rabid dogs at [the Office of the Inspector General] that say, basically, any time you've got any sort of relationship here within the anti kick-back statute, — and quite frankly, they'd like to throw everyone in jail. I've had some very interesting talks with people there. So that's sort of the broad-brush stroke. It's important to keep in mind that the statutes here are, in part, being enforced due to lack of political will-power. There's only so much money, health care costs are rising, and our politicians don't really want to trim back on benefits and a lot of times they're too scared to trim back on provider payments, so what we do and I know Eric [Roth] will go a little more into that is that we will hit them over the head with a lot of criminal penalties and set them straight. [...].

Obviously, there are the statutes, there are regulations, case law, I've given you guys all some of that. The OIG has implemented an advisory opinion process pursuant to the Health Insurance Portability and the Accountability Act ("HIPAA"), 5 and that's been interesting because that allows providers to immunize themselves from prosecution by the OIG under the anti kick-back statutes. Normally that doesn't affect the DOJ's ability to prosecute you, I might add, and that's kind of a big deal. One of the effects of the advisory opinion process, — just sort of as an aside — it's made the anti kick-back statute kind of a nice weapon. Because, if you can submit a request for an advisory opinion, regarding a competitor's practice — say you're going to implement it yourself and get a negative response and you can sit there and wave it in front of the other parties, they're not going to be too happy with their business partners. And if you get a positive response, just go ahead and do it yourself then. It's kind of nice.

Pub. L. No. 104-191, 110 Stat. 1936 (1996).

The government has also published a series on fraud alerts and management advisories on joint ventures and prescription drug managing, hospital incentives, [...] in nursing homes, durable medical equipment, waiver of co-payment and deductibles and arrangements for the provision of clinical lab services, such as free flabotomists or nurses or that sort of thing. So obviously the statute is broad. There are also some informal letters. I just got done writing one myself. We'll submit an informal request to the OIG, setting forth a practice that we believe is illegal, and get a nice letter back saying, "Gee, that's a problematic practice." And then we can wave that around too. [...].

You can also find out what's going on to a degree by just calling up people at the OIG and asking them. That's gotten a little tougher. When I was going to speak here, I called someone at the OIG and I said, "Hey, give me something to say, I'll say anything." And they said, "No, you've got to send a request in triplicate and ship it to our public affairs office, and we might or might not give you a quote." And they also refused to even allow me to say [what] their name is. That shows you how concerned they are about these issues. There are also miscellaneous authorities, there's stuff posted on the internet regarding negotiated rule-making, or the managed care safe harbors. One of the problems that we have with the statute is that it's vague and there's constant tension between the Office of the Inspector General that wants very broad definitions and a lot of discretion to kind of prosecute whatever they see as being fraud and providers who want clear guidance. The problem is that every time the OIG says something, people take it and kind of run with it, find holes in it, find ways around it, and that's like the Stark amendment for example. HCFA has prohibitions on beneficiary inducement now because of holes in the anti kick-back statute. The Balanced Budget Act of 1997 requires disclosures, financial relationships between hospitals and home health agencies when you're going to refer to what a hospital is going to refer. And that's all in response to perceived holes in the anti-kickback statute.

I gave you guys a copy of the Kansas City litigation.⁶ You can look through that. Basically, all [the court] was saying was, "Gee, this statute is so vague, you know, how can anyone realistically have any guidance here?" And I think that's true. To a degree, the OIG has done that themselves. They've defined, in the past, the concept of "induce" under the statute as, "to lead, move, by influence or persuasion." It's extremely broad. Basically, if I give Mark [Langdon] a pen, and it says, "Pharmacy Company X," I've violated the anti kick-back statute, right, that's pretty broad. People have tried to be

See supra note 1.

reasonable. A very large court case called Hanlester Network v. Shalala, said that "induce is to bring out or about, to effect, to influence, to cause or to act on" [...] — took the Black's law dictionary definition. It said that, "induce is nowhere defined simply by reference, to influence, or encouragement. Induce connotes an intent to exercise influence over reason or judgment." It's a higher standard, in other words, and there's this tension because the OIG wants to be able to get you for absolutely anything you can do. And the problem is that courts are starting to get a little resistant to that, but again I point you to the Kansas City indictment as being an example of the OIG going a little too far.

The policy underlying the statutes — I guess there's five major considerations. There's cost. The statute is implemented when providers were essentially cost-based and as I discussed we made a political decision to reduce cost by labeling practices fraudulent. Access is a concern, and the theory is that people entered to exclusive relationships because there's money flowing between the parties and that might impact patient care, which is another concern. Quality and interfering with medical judgment of physicians is a concern. Asymmetry of information is a concern. Fraud can be hard to spot, especially when there's a medical decision involved. The anti kick-back statute gives a weapon that allows the government to prosecute you for violating the statute without having to prove that you made an inappropriate medical judgment. Government, - FBI agents are not too qualified to determine if care is medically necessary, but they can sure nail you under the statute. And uncertainty. The government doesn't know what's hanging on out there. They won't know what's going on in the real world. But the antikickback statute gives them a weapon to fight back fraud.

I gave you guys a quick overview, an analysis of how the statute works. Does it apply? Does the situation you're in fit under a safe harbor exception? Realistically, it almost never does. So you're left with the facts-and-circumstances analysis; you're in "never never land." You don't know if you're going to get prosecuted or not. When you fall into that "never-never land," you've got to take into account a series of factors, financial harm. For example, managed care programs, there might be less potential financial harm, but there might be a risk that you're swapping, so what you might be doing is giving a discount to managed care patients in order to pick up Medicare business and that's kind of a big issue.

Another risk factor is that you're substantially in compliance with the safe harbor — that goes to the intent of the parties. Changes in the utilization

⁷ 51 F.3d 1390 (9th Cir. 1990).

⁸ See supra note 1.

levels: If there's going to be an increase in the business between the parties, that could be a red flag for a care intermediary to bust you. Also, if you're in an industry that's growing rapidly, you've got to be a little more careful, and that's just a pragmatic concern. Impact on access to care is a concern. Informants: The OIG gets people ratting on their competitors all the time. That can be fun. Enforcement Activity: If the government is cracking down on your industry around a particular practice, you've got to be more careful. You've got keep an eye on the OIG work plan, special fraud alerts. Resources are an issue; if the government doesn't have the resources to delve in and uncover your particular arrangement because it's complicated, there's less of a chance you're going to get nailed. The risk of liability: How likely is a court or administration body to conclude that someone's knowingly or willfully engaged in the conduct that violates the statute? [...]

Impact on quality: ... some practices can actually increase quality. Some form of companies provide disease management services to managed care entities use for example. State statutes you should be concerned with: the states have parallel statutes for the anti-kickbacks. Some are all payor; those are important. Practical factors: how far out does the OIG or DOJ want to be seen as going? They don't want to go out on a limb and ban something that's completely common in the industry if it's really not harming care. And that's a political concern as well. In the profile the entity or the practice involved if the OIG can get a multi-state big reward settlement they might be inclined to go after someone. Visit Columbia/HCA getting nailed for stuff plenty of other people have done. No one has really complained about it. There's also a concept that they like and that's holding someone out as an example and beating them up in public to kind of scare everyone else off. Finally I'd point out that in a transaction the anti-kickback statute — because it's so vague, can be a tool to leverage negotiation. If you can point out to the other side ways that their agreement is structured, it might need a little more work. Sometimes you can negotiate more favorable terms for your client on the argument that you are assuming a little more risk. And I'll stop it right there.

ERIC ROTH: O.K. Thanks. Well I'm going to talk a little bit first about compliance programs given the growth of the managed health care industry, the competitiveness within the industry and the fact that the difficulties encountered in understanding these statutes may cause companies or their employees to run afoul of them and get them in trouble.

One of the best prophylactic measures a company can take is to implement a compliance program under the United States Sentencing Guidelines. Having this type of program in place will help substantially to mitigate the penalties and fines that the company may incur if it has been found to have violated one of the statutes or other statutes that we have been talking about. In order to be

considered a compliance program, the program must be designed to prevent and detect violations of the law. And the company must exercise due diligence in seeking to prevent and detect criminal activity. So, they must establish a system, a corporate-wide system, of standards and procedures by which employees are expected to abide. There must be specific individuals within the company who are assigned the responsibility to oversee compliance with the established standards of conduct. Another one of the requirements for a compliance program is that the Company not delegate the oversight responsibility to somebody who it knows or should know has propensity to engage in illegal activity. It sounds kind of obvious but that's one of the requirements.

The organization must also take steps to effectively communicate the standards and procedures to all the employees. One of the ways we do this is making sure that the company will hold training programs for employees to learn what the standards of conduct the company expects are. Other ways to do this are to disseminate written materials to the employees. Oftentimes we will do both. The organization must take reasonable steps to achieve compliance with these standards by setting up monitoring and auditing systems within its own company to detect any violations or detect things that are running afoul of any of the statutes we talked about. And, upon finding any violations, it must take actions or have in place methods or mechanisms by which it can enforce some discipline, whether it be through termination, suspension, etc. And the Company must take reasonable steps or have reasonable steps in place to ensure that it does do something to prevent further violations of the various laws.

The precise acts or programs within the compliance program depend upon several factors, — the size of the program, the prior history of the organization [and] whether the organization is in a business that has a particular risk of violations. For example, to go outside of the health care industry, if you have a company dealing with toxic waste, — you know disposal of toxic waste is likely to be an issue that is one that they need to be looking out and focusing their compliance program on. Here we have been talking about the anti-kickback statute. The conduct prohibited by that statute should be a focus of a compliance program.

The benefits of, as I started out by referring to, — the benefits of having a compliance program in place, to begin with, are that it will severely limit or reduce the liability of the company. Or, in the event the Company is found liable, it will severely reduce or limit the penalty that it suffers. And some case law suggests that not only the company but its board of directors can be held liable for violations when they have not had sufficient compliance programs in place to monitor and find out what kind of activities are going on. Obviously having the program in place will help to deter misconduct by

employees. It also will help with the prosecutorial decisions if the company can show it has done everything it possibly could to prevent the misconduct. Prosecutors might want to look somewhere else where there have been more blatant violations; in a company that had no oversight capacity whatsoever. And another thing, not only is it good to have a compliance program from the standpoint of employee morale but also for the sake of reputation within the community as being a health care company that's at the forefront of policing itself in order to avoid potential problems.

[...]

We have had occasion to set up [...] compliance programs. I think the impetus for setting them up has been — there have been some problems. They recognize, I guess, it's kind of a slap in the face. They recognize they need to do something and make sure they have got something in place that they can point to in the event something really serious happens. Not that what we've discussed wasn't serious, but it never really mushroomed out. So, no we haven't had any resistance from people saying no I don't want to spend the time, effort and money to establish one. It's really not that difficult to establish it, it's another thing to make sure it's properly implemented. The bigger the organization perhaps the more effort it takes to implement one and make sure its effective.

TIM RAVICH: [...]