Fraud and Abuse Panel

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Zach Gureasko: All right. If you can all take your seats, please, we’re going to go ahead and get started again. I am going to introduce our moderator, Daniel Patten. Before I do so, Aubrey briefly alluded to our online Health Law Journal. I just wanted to make you guys aware of a particular date. We accept practitioner’s submissions and we accept them on a rolling basis, but we basically have a deadline in the spring and a deadline in the fall. We don’t have the fall set up yet, but the deadline in the spring is March 3rd. Some time within the coming days, the person in charge of our website will open a portal where you can drop your submissions, and this can be anything from a full article to a short essay. Ideally something longer than maybe you would see on like a blog post, but just, you know, anything you have that you want to submit to us, we are happy to take. Again, that deadline is March 3rd and that will be through a portal on our website. Then we’ll have selected those submissions that we will publish by March 31st. Again, we’ll be accepting them at any time, but we just have two firm deadlines

* The views of Ms. McIntyre expressed here are her own personal views and do not necessarily reflect the views of the U.S. Attorney’s Office or the Department of Justice.
just to enable us to kind of review the things that have been submitted, discuss, and decide which ones are going to be published. The second part that I wanted to talk about is the blog that we have on that website, again, healthlaw.belmont.edu. The blog is student led and we’re going to keep it updated regularly with the happenings in the health care community. As we all know, these change every hour in the health care community so we’re going to keep that updated very frequently with submissions from our students. So I just wanted to get that deadline out there as well as generate some interest in the blog, and have you start looking at that for some guidance in some of these issues that we’ve been talking about and will continue to talk about.

Now, we’re going to have a panel discussion on some concerns that we have about value based reimbursement structures, and our moderator is going to be Daniel Patten. Daniel graduated with his Bachelors from Wake Forest University, and then he received his J.D. here at Belmont University College of Law with high honors. While he was here, he received the Health Law Certificate and the ABA BNA award for excellence in the study of health law. He was also the executive editor of the Belmont Law Review and he is now in his third year working for Waller in the health group focusing on transactional and operational issues. He’s going to go ahead and introduce the rest of the panelists, but if you’ll join me in welcoming Daniel Patten.

Daniel Patten: Thanks, Zach. I’m excited to be here, back at Belmont. Just before we begin I want to say that the quality of the health law program Belmont has established is a testament to Debbie Farringer’s hard work. All of these questions originated from student questions and ideas, which made my job a lot easier. I want to thank the students for putting that together. The panel today consists of two private practice attorneys and one government attorney. We have litigators and regulatory attorneys, so a good mix of attorneys across the spectrum.

Starting on the far end is Brian Roark, who is the head of the Bass, Berry & Sims healthcare fraud task force. He’s also an adjunct professor at Vanderbilt University, teaching Fraud and Abuse and is the chair of the health law section of the TBA.

To his left is Ellen Bowden McIntyre, who is an assistant U.S. Attorney in Nashville. She has been there since 2003 and handles various cases primarily on the False Claims Act\(^1\) and other health

care fraud, on both the civil and criminal side. She attended Penn and received her J.D. from Columbia Law. Before she was an AUSA, she served as a senior trial attorney at the Justice Department’s Civil Rights Division, and worked as a staff attorney at the Southern Poverty Law Center.

Finally, to Ellen’s left, is Patsy Powers. Patsy is a partner at Waller and her office is two doors down from me, most importantly, right? She earned her B.S. at Vanderbilt and her J.D. at Tennessee College of Law. Patsy serves on the board of the Sloam Family Health Center.

So, to kick things off for the Fraud and Abuse panel, I would like to start with the private practice attorneys. What are some current challenges for clients, and where do you see the biggest challenges for your clients today in connection with the appliance of fraud and abuse? Additionally, what are some potential effects or potential concerns moving forward with the repeal of ACA?

Patsy Powers: Anybody who’s in the healthcare industry is familiar with and used to change. They’re used to changing laws, changing regulations, and to a certain extent, changing enforcement. But, I think, what we’re seeing now, is a wave of change that is far greater than what most people have ever expected. It’s not only related to the Affordable Care Act but also the changing enforcement climate. My favorite example is employment of physicians. For years, employing physicians was the safest way for a hospital to engage with their practitioners because there is an applicable safe harbor, an exemption under the anti-kickback statute, and a Stark Law exception. It was very easy for hospitals to employ physicians if the parties were not in a corporate practice state. And so, assuming that you are not in a corporate practice state, it was a nice way to go. Recently however, although the law hasn’t changed, and the regulations haven’t changed. The qui tam relators became very active, with the result being that the enforcement climate has changed. The result is that the definition of “commercial reasonableness,” an element in the Stark Law employment exception, is closely scrutinized by whistleblowers. The most obvious scenario is a physician whose professional collections are less than his salary. Absent countervailing circumstances like high indigent population, poor payer mix, or difficulty retaining a specialty, the relationship may be prosecuted as an arrangement that

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4 Id.
5 Id.
is not commercially reasonable. The enforcement climate has upended our view of what’s safe, what’s comfortable, and what are safe financial relationships for our clients to have with physicians.

Brian Roark: Yeah, I would agree with Patsy. The biggest challenge is the overwhelming complexity of the laws and regulations that are out there. But as Patsy said, that’s already baked into the DNA of a lot of health care companies. I would say that one of the biggest challenges today, in particular sometimes for smaller health care companies, is dealing with so much regulation or so many different outside entities that are looking into what they are doing that forces them into a position of having to be a lot more reactive than proactive. One of my clients used a term this week that I like a lot, which is they sometimes feel like there is “regulatory harassment.” That many times, obviously excluding Ellen, sometimes in the government there can be a tendency to paint with a broad brush. A lot of companies out there feel like they are really trying to do things the right way, but that doesn’t mean that they are always perfect, and many times they may violate a particular regulation. Sometimes the government doesn’t see that and appreciate that the cost of dealing with an investigation or defending a matter—just the cost of that—even if they’re ultimately able to show that they didn’t do anything inappropriate, can be overwhelming. And I would say, one of the big things that we’re watching in my sector on the litigation side, is not necessarily just changes in the ACA and what may come from that, but what’s going to happen with government enforcement under the Trump administration. Health care fraud enforcement is not a partisan issue. Just because the Republicans are now in charge doesn’t mean that fraud enforcement is going to decline. One of the biggest proponents of the False Claims Act is a Republican senator from Iowa, Senator Grassley. That being said, we are waiting to see how the Trump administration may change focus. Is there going to be more focus on areas like immigration, and is that going to mean less enforcement on things like health care fraud? And then I just want to mention, locally, there is a great article that came out yesterday in the Nashville Scene about what may happen with changes with U.S. attorneys and with judges in Nashville. The article features a lot of interesting quotes from Dean Gonzales here at Belmont, reflecting on his experiences as Attorney General. Plus, we’re waiting to see if there is a new U.S. Attorney in Nashville and how will that change the focus. And then, news from just yesterday, or two days ago, the

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Middle District of Tennessee has four judges, lifetime appointments. The Chief Judge in Nashville, Kevin Sharp, announced that he is resigning and stepping down from the bench and is going into private practice. Interestingly, he is going to open the Nashville office of a qui tam whistle blower law firm, Sanford Heisler. So read into that what you will. But you know, it’s extremely interesting in Nashville that you have someone leaving lifetime appointment who’s going to go over and do plaintiff’s side health care fraud cases.

**Daniel Patten:** Talking about the False Claims Act, which I think we all agree is a well-used arrow in the quiver of the government, last year the Supreme Court decided a case of Universal Healthcare in *U.S. ex rel. Escobar v. Universal Health Services, Inc.*, which analyzed the theory on implied false certification that many courts have been using for purposes of determining liability under the False Claims Act. Ellen, if you could tell the group who might be unfamiliar with this issue, a little about the background of the case, the circuit split, and discuss this new definition of materiality. How, under *Escobar*, pleadings may have changed or just generally how it may have changed the litigation of these cases.

**Ellen McIntyre:** Sure, and just a tad bit of background on the case in case folks here haven’t read it. Basically, it came out of a Massachusetts District Court False Claims Act case, in which a Medicaid recipient had gotten services from Universal Health Services, which gave counseling services, prescribed medicine, and that sort of thing. It turned out that 23 of the providers there actually weren’t properly licensed to be doing what they were doing -- like they had nurses who were not supervised who were prescribing medications. All this was in violation of Medicaid requirements in the State of Massachusetts. But these requirements were not expressly designated as a condition of payment. And so, therefore, a whistleblower filed a False Claims Act lawsuit, and the District Court granted the motion to dismiss because this violation — although clearly not legal — was not expressly designated as a condition of payment, which has been an issue brewing in the circuit courts. The case winds up at the Supreme Court, and the Supreme Court had two big rulings. Number one, an implied certification, in other words, submitting a claim in which you’re not complying but you’re not saying, “I am complying,” can be an actionable False Claims Act violation. So the Court endorsed that theory, which was mostly endorsed out there but there were still some arguments about it. So that can be a basis for liability, and it can constitute a

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misleading half-truth, the term that the Supreme Court used. The Court also said that you don’t have to have an express condition of payment. It is relevant and you can look at that, but the absence of an express designation of a condition of payment is not dispositive. You can look at other things. The key question is materiality, and that’s the other big ruling. Escobar gives a big explanation of what the Supreme Court expects the materiality standard to be, and the Court tweaked that language a little bit. So what the Court said about materiality is that you can look at it from two perspectives: one is the perspective of a reasonable person and would they think that something is a material condition of payment. Or, you can also look at it from the perspective of the likely or actual behavior of the recipient, even if a reasonable person doesn’t value it. So you sort of have two doors that you can fit through whether you’re a regulator, or the U.S. government, or a state government. And so, that’s obviously a significant ruling, as a June 2016 Supreme Court case.

The other part of the question was how pleadings change. From the government’s perspective, I don’t think it really changes so much about what we thought was required, but clearly the language is a little bit different now. Like for one, I don’t think we were focusing on reasonable person or, putting conduct in specific, linguistic boxes. So I think it’s definitely true that if the government files a complaint in intervention in a qui tam or if we file our own original case without a qui tam, the government is going to try to track that Escobar language and fit within that language. I think we were already basically doing that. But having said that, the government is going to be more careful, and probably good lawyers are going to be more careful in the way they plead things. Obviously these arguments are going to come up from the defense, and I would let Brian segue into that, but this is the new standard. It is not really that different from the old standard.

**Brian Roark:** Yeah, the government has been taking the position that Escobar did not really change anything. The defendants, on the other hand, say it’s a radically different and much higher standard in terms of what a plaintiff has to show to be able to establish liability under the False Claims Act. The example that I like to use to talk about Escobar is alcohol-based hand rub dispensers because nobody ever expects to talk about that. There are, please look it up afterwards, there are significant federal regulations specifying for hospitals, for ambulatory surgery centers, not only that they have to have alcohol-based hand rub dispensers but how they’re supposed

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9 *Id.* at 2001.
10 *Id.* at 2003.
to be installed, and where they can be and where they can’t be. That is a federal regulation. If you think about that being on one end of the continuum, that if a hospital violates that regulation in some way, really nobody thinks you can bring an FCA case on that basis. On the other end of the spectrum, let’s say you have the Anti-kickback statute or the Stark law. If you violate the Anti-kickback statute, everyone understands you can be sued under the FCA for that. So if those are the two ends of the spectrum, you have all this area in between of the thousands of regulations that are out there. If you violate this particular one, does that subject you to FCA liability? Does that mean you potentially, by being in violation of that, in billing Medicare that you might be required to make a repayment? And Escobar attempted to weigh in on that question, but the parameters it has put around that question in some ways has made it harder for providers these days. Previously, the rule was more around if something is labeled as a condition of payment, then you could be liable under the FCA. But if it’s labeled a condition of participation, if it just goes to a survey issue, you couldn’t. The Supreme Court said we’re not going to apply the test that just looks at that label because that would make it too easy for the government to put that label on every single regulation. Instead, we’re going to get into “do you really think that this is essential to the services that are being provided?” But I mean, Patsy, in your practice has this made it harder?

**Brian Roark:** And I would agree with Ellen, that Escobar is not changing very much the kinds of cases that the government is going to be bringing under the FCA, but you still have to deal with a lot of these crazy whistleblowers and relators out there, who might really might bring an FCA lawsuit about hand dispensers or something else. The government may decline that lawsuit but more and more often defendants are still having to go and litigate with relators over some of these issues.

**Ellen McIntyre:** It is true that getting rid of the condition of payment—sort of bright line test—makes it easier for the government to bring certain cases where there wasn’t an express designation, because that limitation has now gone away. Now there is still a test obviously. But yes, I agree, it is a subjective test.

**Daniel Patten:** So moving from the relator or the government coming after providers aspect of the False Claims Act, I would like to focus on the self-policing aspects of self-disclosure. CMS and

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OIG, the protocols they released have been out for some time. I know on the CMS side, the increase in volume and the response has been quite delayed. Patsy, could you speak on where you see the system right now? Has the government been effective in communicating or clarifying that process? Do you think that process is developing in a positive way?

Patsy Powers: The process is a mystery. The positive aspect of the CMS Self-Referral Disclosure Protocol is that the final settlement amount is much less than the penalties due and owing in an initial disclosure. The CMS disclosure protocol for Stark violations generally is that you disclose to CMS each way that you violated Stark and the amount of money that you owe back to the government for each of those violations. Then you get an email from CMS confirming they received the disclosure. It’s often years before you hear anything else. Sometimes it is difficult to even identify the person reviewing the disclosure. You have to really work with CMS and find the right person, and even then, CMS won’t tell you anything. Similarly, on its website, CMS identifies past settlements and the amounts of the settlements, but not the amount that was originally submitted with the disclosure. But by word of mouth and experience, we’ve learned that the settlements generally range between six to ten percent of the disclosed amount received by the provider from claims tainted by a Stark violation. So if it’s a $70 million disclosure, then the settlement may be $7 million. So that’s helpful because that takes some of the difficulty away from the process when you can advise a client that even though they disclosed $10 million in tainted claims, they will probably have to pay less than a million dollars. But there is no certainty to that six to ten percent range. That’s just been the typical experience so far, which is better than it could be, CMS could be trying to collect 100%. There is also a lot of conversation in Washington about changing Stark and maybe keeping the prohibition related to physician investment in entities that provide designated health service. CMS certainly has reduced the burden of Stark in certain respects with the changes that came about last year. For example, CMS clarified that the written agreement requirement for certain compensation arrangements can be satisfied by a collection of either emails or letters or documents or board minutes that can be pieced together to establish a written arrangement. CMS also lessened the rules for


holdover leases so that the time period for a holdover, rather than just being six months, can continue for a longer period of time so long as the rent paid during the holdover remains fair market value. So, while CMS has lessened the burden a little on providers, the disclosure process is really a black box. And, at the end of the day if CMS comes back and says, “You owe us a million dollars,” there isn’t a discussion about it. It’s just, “here’s where you are,” which is a little disturbing because providers don’t really have any opportunity to discuss it, negotiate or anything.

**Brian Roark:** Yeah. I would agree. CMS has really pushed and encouraged providers to use the self-disclosure protocol. At the same time, CMS discloses very little information about matters that have been successfully resolved. So if you’re a provider, there’s very—absent being able to talk to another company about what result they had, absent being able to talk to an attorney who might be able to share information about a past experience—there’s very little insight. At the end of the day, if we have a client that finds a very obvious issue, you’ve been paying a physician and there’s no written agreement and there’s nothing to argue that there’s a written arrangement, they will use the Stark Self-Disclosure Protocol. But for other issues, we really look creatively for ways to not.

**Daniel Patten:** So, we talked about False Claims liability often being connected to liability under the Anti-Kickback Statute and the Stark Law. Anti-kickback being the foundation for a lot of these claims, which came about in contemplation of a fee-for-service system. Today, however, reimbursement is switching to more of a value-based system. CMS has announced that its goal is to have 50 percent of all reimbursements for medical services under value-based reimbursement methodology. How will we see this shift? How will that impact the fraud and abuse laws? Are we going to see more waivers? Are they going to lose their teeth? Could this have downstream impacts on FCA, litigation and potential lawsuits in the future?

**Patsy Powers:** That remains to be seen. The whole premise of the Anti-Kickback Statute and Stark Law, in respect to payments to physicians, that the payments are fair market value. Under value-

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based payment models, payments to physicians should still be fair market value. Of course, with some value-based payment models there may be a bucket of shared savings to be divided among physicians, a hospital, a home health agency, etc. If for example, you go to a hospital for a hip replacement and each of the various providers sufficiently participate in the patient’s care, then each of the providers should enjoy the benefit of the shared savings money. If, however, any of the money paid to a physician is above fair market value, then is that a problem? It shouldn’t be, which is partially why the ACOs have waivers to the anti-kickback statute and Stark Law that are broad, you just have a waiver. For other arrangements, there need to be similar waivers to protect reasonable payments to physicians. The prior panel talked about how the commercial payers, Medicaid, and Medicare all have to have, to some extent, a common payment methodology so that providers do not have to abide by different programs and arrangements. And so, if say a commercial payer and Medicare each have similar requirements for bundled payments, then that works very well in terms of care delivery and the documentation required. But, the money from each payer might not be the same. Dr. Farringer might receive $10,000 in bonuses for patients treated efficiently while participating in a bundle for Blue Cross and a substantially similar bundle for Medicare. The question then becomes whether that $10,000 payment is for the right mix of patients or not. In other words, is the right amount being attributed to Medicare versus Blue Cross? Should providers really have to track that? Should they have to track whether or not that’s a fair market value allocation of the bonus for the commercial insurance, Medicare and Medicaid? That would be very difficult and that sort of compliance effort arguably shouldn’t be necessary. If you’re doing the job well, you’re providing quality service and you’re engaging in these alternative payment models, should you really have to worry about fair market values? And so more waivers, I think, are appropriate. But in the meantime, we’re sort of living in both worlds. And that is what Michael was saying—it’s a challenge, operating a hospital right now in all of these different worlds is a huge challenge. So yes, more waivers are necessary.

**Brian Roark:** As Daniel phrased the question; the Anti-Kickback Statute and Stark Law rose out of a fee-for-service reimbursement system, with the thought being that those laws were the proper ways to govern excesses in that type system. As we move away from fee-for-service reimbursement, we move towards encouraging more integration between the hospital and rehab, or the hospital and a home health company. Arrangements that are viewed suspect under Stark Law or Anti-Kickback are exactly what the government or
payers are trying to encourage these days and the law no longer fits that. I wish that I were smart enough to say, “Here are the ways to change the law.” It’s either waiver, or it’s either when we’re dealing with fee-for-service kind of payment structures, potentially doing away with it all together.

Daniel Patten: For the litigators here, do you see any issues that are starting to arise in district courts and courts of appeals in connection with fraud and abuse laws that have an impact on current approaches to compliance?

Ellen McIntyre: Well in general, of course, there’s just more qui tams. This means both that the government ends up intervening in more qui tams, but also that the government still declines a chunk of qui tams. One change is that a lot of those relators are going forward without the government, which didn’t used to happen. Now obviously this has spillover effects in terms of what providers do, and it probably is sort of a policing tool, even if it hasn’t hit a particular provider with a suit being filed against them.

There is also of course a huge increase in recoveries annually by the federal government. I think that the government got an additional billion dollars over last year. These are gigantic numbers. I think also that it’s not so much based on a change in the law, but just kind of a change in the climate, with all of these factors.

There is also an expansion of things that the government is looking at, and not just in terms of what comes in the door and what a whistleblower might file. Such as, in our district, in the Middle District of Tennessee, we are one of ten districts in the U.S. that launched its own Elder Justice Task Force in 2016.20 The Justice Department has also created an Elder Justice website, which is a new initiative. There are various ways in which most people might not think of Elder Justice, for instance, as something that could be the subject of a False Claims Act action. But elder issues are increasing around the country. Look at skilled nursing facilities, look at the quality of care concerns. Quality of care is probably increasingly going to be something that the government looks at when they’re thinking about False Claims Act concerns and how it impacts patient care. Are patients getting what they should be getting? As opposed to the Purell example. I don’t think we were ever focusing on Purell. I’ve never seen a case about Purell.

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Brian Roark: Not yet.

Ellen McIntyre: I’m not going to say too much about that. The government is concerned about serious violations that impact patients or the government fisc in significant ways. Sometimes people just think about only hospitals being affected, and I don’t mean that the hospitals don’t have to comply, but it’s sort of a big picture. The big picture is just services that Medicare and Medicaid fund, and whether there are substantial false claims in conjunction with those services across the board. That’s my general insight.

Brian Roark: I would add a couple of trends that I have seen: One, the government’s increasing use of data, which is not a new trend for you all here, but more of just—I think in the past, for a lot of AUSAs like Ellen, if they wanted to analyze some data, that would require making a request and getting some specialists to come and help them. These days, what I have seen is that it is just much easier for AUSAs, while they’re on the phone with you, to be able to pull up on their computers and see for this particular doctor, is this doctor fiftieth percentile for whatever particular procedure, is this doctor ninetieth percentile, is this doctor off the charts. Also, where the government may start an investigation looking at issue A: Someone files a qui tam, a qui tam makes allegations about this doctor’s lease arrangement. The government looks into that and finds that there’s not really support of that. But, oh by the way, as long as they’re looking into that doctor’s lease arrangement, what they do notice is this doctor appears to be an outlier with respect to how many stents he or she is doing in the state of Tennessee versus other doctors. I’ve been amazed at how much of this data you can even pull up on the Wall Street Journal or the Open Payments website just to see for a particular physician, you know, if the number one doctor in the state—or number two doctor in the state for stents that $3 million in Medicare reimbursements last year. It sort of stands out if number two is $3 million and number one is at $9 million. It stands out, and the government, in my view, is paying closer attention to that. The other item that I would mention that is really significant right now is what’s going to happen in terms of statistical sampling. If the government is investigating conduct that went on at ten different facilities, if they say we think these ten facilities are providing too much therapy or therapy at too high a level, and we think that that touches on 40,000 claims over this time period, the government wants to move forward on a medical necessity issue. Can the government simply put on proof on what happened with respect to 40 patients and say that that then extrapolates across the 40,000? Or

is the government obligated to go and prove fraud with respect to, brick by brick, each individual case? It’s the difference in, is the trial going to last one week? Is the trial going to last one year? The scary part about a trial lasting one-week is it makes it very easy for the government to be able to bring some really massive fraud cases and have a big swing in the balance just based on how the proof may come in on a handful of patients.

**Daniel Patten:** Do you see an increase in relying on contractors, such as ZPIC’s? It is a good way to provide oversight at a low cost to the government.

**Brian Roark:** I see it continuing. I think under a Republican administration, that you will see more outsourcing and the continued pushing of audit and compliance function to outside third parties and giving them some incentive to go and find the fraud. I think there’s some scary stuff going on in some jurisdictions right now. In the state of Florida right now, long term care and home health, just sort of some out of control payment suspensions that the ZPIC in Florida has been instituting right now. In a system where you’re dealing with a ZPIC, if they’re out of control, what do you do about that? You know, if the ZPIC doesn’t work for Ellen, and I’m not really sure that they work for CMS. They can put providers into difficult circumstances with few ways to make that stop.

**Ellen McIntyre:** Although, I think that’s usually discussed with CMS. But yes, I think there are more payment suspensions. I think that’s correct.

**Patsy Powers:** The data issue is a big one. The government has access to all kinds of data, and that’s only increasing as our delivery systems and payment models become more sophisticated and providers collect and report more and more data on quality, outcome, utilization and more. For example, data about how many times I tell my doctor I might take my medications each month, very personal health data is being collected. There are all kinds of data that a provider is required to report under new payment systems, and we don’t know yet all the different ways that a provider might accurately report or inaccurately report. But we do know that there are, and likely will be, ways for a provider to increase their reimbursement depending on the data reported under these new payment systems after 2019. So, the use of the data, the accurate reporting of the data, and the accurate review of the data is going to transform things significantly. It’s not clear yet how this transformation will play out. But it could be very, very significant, depending on how these third party contractors who are empowered
to review the data, slice and dice it in different ways. A provider might not even know who’s looking at their data.

**Daniel Patten:** For the last few minutes, I want to open it up for questions.