Mr. CRAPO. At the top of page 2 this letter it states, "We recognize that it is the responsibility of the Department of Health and Human Services, HHS Office of the Inspector General to conduct FDA employee misconduct investigations. It is the practice of the OIG, however, to assign its investigators to cases that demand priority attention, including the most serious matters involving fraud, waste and abuse. Therefore, as a practice the OIG historically has referred most employee misconduct allegations back to the FDA for investigation."

As we have learned from the good news, bad news memorandum by Ms. Bianchi relative to the Myo-Tronics case, an apparent criminal violation involving the chairman of an advisory panel who is a special FDA employee for that purpose was not referred to the OIG and then sent back to the FDA. This appears to be a clear violation of the responsibilities of the OIG as stated in the Thompson letter. Do I understand that correctly?

Mr. KESSLER. I'm sorry.

Mr. CRAPO. If I understand the letter that was sent to us by Diane Thompson, the responsibility for these matters is to send them to the OIG for referral and evaluation, and then if the OIG determines that they are not of sufficient seriousness, they will send them back to the FDA for its internal investigation. Yet that was not done in the case of the advisory panel regarding the Myo-Tronics case and the reference of the FDA employee. Was that a violation of the policy not to refer that issue to the OIG?

Mr. KESSLER. Congressman, we'd have to ask our Office of Internal Affairs and the Office of Inspector General on the specific case. I am responsible for setting up the Office of Internal Affairs. It was set up in consultation and in conjunction with the Office of Inspector General.

We always had as part of our ethics program an investigative arm that worked with the Inspector General. I thought that investigative arm was very weak, and we put trained, highly professional people in conjunction with the Inspector General. My instructions in working with the inspector general is that our Office of Internal Affairs works very closely on all matters with the Office of Inspector General.

I know for a matter of fact that the Office of Special Counsel for Ethics in the Department that always works with the Inspector General is involved in that along with the Office of Internal Affairs.

I don't have personal knowledge about how the Office of Inspector General and the Office of Internal Affairs are coordinating this particular case.

Mr. BARTON. Will the gentleman yield?

Mr. CRAPO. Definitely.

Mr. BARTON. Dr. Kessler, the question is, as I understand it, why did your Agency not refer this instance to the Inspector General?

Mr. KESSLER. I'd have to ask our Office of Internal Affairs, Mr. Chairman, whether or not it was referred. I don't know the answer to that.

Mr. BARTON. You have got 10 people with you, approximately. You have got the brainpower trust of the entire FDA with you. Surely one of them can answer that question.

Mr. KESSLER. Perhaps one of them knows the answer. I don't think there is anyone from the Office of Internal Affairs.

Mr. BARTON. Then let me ask the question. Can anybody who is a representative of the FDA give Representative Crapo a straight answer to his question?

[No response.]

Mr. BARTON. Silence says that they cannot.

Mr. Crapo, would you please continue.

Mr. KESSLER. Maybe Ms. Pedersen can answer. Let me have Ms. Pedersen answer the question. She has some knowledge.

Ms. PEDERSEN. My name is Amanda Pedersen. I'm FDA's Chief Mediator and ombudsman. It is my understanding that our office was involved in referring this matter to the Office of Internal Affairs for investigation. Their process is to develop some of the facts, look at some of the documents, and consult before any decisions are made with respect to the matter intimately with the Office of the Inspector General or the Department of Justice. That is their call, but they are performing here as an investigative function that will lead to that consult. I believe that is part of the arrangement that they have with the Office of the Inspector General.

Mr. BARTON. Dr. Kessler, you or your associates, we would hope we would get the answer for the record. On what factual basis was the decision made not to refer this to the Inspector General? A review of the statute, at least based on my staff's review, is that it should have been. We have documents that we will put into the record that build the case that it was not referred, at least on appearance's sake, as part of some effort to cover up impropriety.

Mr. KESSLER. Mr. Chairman, those are strong words.

Mr. BARTON. I chose them very carefully, Dr. Kessler.

Mr. KESSLER. I understand that. I would ask that you for the record allow the Office of Internal Affairs to get the answer of how they are coordinating this investigation. They should be coordinating this investigation. They should be working very closely with the Inspector General. That's how the office is set up. If you are aware that they are not working together, then I would be happy to look into that and work with you on that.

Mr. BARTON. Thank you.

Mr. CRAPO. Let me go a little further into this. It's my understanding from the good news, bad news memo that there was an apparent violation of a statute and that there was discussion to determine whether or in some way this could not be referred to the OIG. Let's not get into the details of whether that did or didn't happen. Let me just ask you this. Is it the policy of the FDA that these types of cases, in other words, an allegation of employee misconduct that could involve criminal misconduct, should be referred to the OIG, or can the FDA handle them through its internal Office of Investigative Affairs.

Mr. KESSLER. It is my understanding, Congressman, if there is credible evidence that meets a certain threshold that certainly the Inspector General should be involved in the case. The Inspector General may choose to rely on certain investigative forces of the internal affairs. That's the way it should work.

Mr. CRAPO. Who makes that decision? The question I have is this. Is the decision as to whether it reaches the level of credibility made by the OIG or by the FDA?

Mr. KESSLER. That should be done in consultation. The Office of Internal Affairs that I set up has 1,811 trained investigators. They are highly professional. Their instructions are to work in very strong collaboration with the Office of the Inspector General. I certainly would hope that that is happening.

Mr. CRAPO. I would like to get a little further clarification of what your answer is. It's my understanding that the statutory responsibility for these investigations rests with OIG.

Mr. KESSLER. I would agree with that.

Mr. CRAPO. You would agree?

Mr. KESSLER. I would certainly agree that in investigation of criminal conduct activities the Inspector General has to be involved, and our Office of Internal Affairs should be working very closely with the Office of Inspector General. That's how I set up the office. That was my intent.

Mr. CRAPO. Then if there were a failure to refer such a case to the OIG, would that be a violation of the policy? Would that be a violation of the law?

Mr. KESSLER. They should be working very closely on all the facts of the case, yes. The Office of Special Counsel for Ethics outside of the Agency is involved in the Myo-Tronics case. We use the words "coverup." The Office of Special Counsel for Ethics is involved. I have knowledge that they are aware of that. So I think there is collaboration going on.

Mr. CRAPO. If I could just ask one other quick line of questions, Mr. Chairman.

Mr. BARTON. Mr. Crapo, the gentleman's first 10 minutes has expired and the ranking minority member has two other hearings. I will recognize him and then attempt to come back to you before you have to leave.

Mr. CRAPO. Thank you.

Mr. BARTON. In all fairness, we've had 10 minutes.

The Chair would now recognized Mr. Deutsch.

Mr. DEUTSCH. Thank you, Mr. Chairman.

I'm going to start with an overview of some FDA self-investigative capability, just sort of walk those on with the FDA. One of the industry's concerns seems to be that the FDA cannot or will not investigate allegations of misconduct or misbehavior involving its employees, but since your arrival at the FDA the Agency has taken several steps to improve its ability to investigate these kinds of allegations.

Can you describe for us what you found when you started at the FDA, what changes you have made, and why you believe they were necessary?

Mr. KESSLER. Congressman, I came to the Agency right after the generic drug scandal. There was widespread misconduct both within the industry and with several bad actors within the Agency. That had an enormous effect on the public health. We have set up since then an Office of Criminal Investigations; we have set up an Office of Internal Affairs; we have worked very closely with the Inspector General.

Six FDA employees—I believe the number is 6—since I've been here have been approached with bribes. They came in and they worked with the Inspector General and our folks. They were willing to risk their own safety. They wore wires, and arrests were made. That's what should have happened in generic drugs. If you take a GS-5 or 6 and they are approached with a potential bribe, similar to what happened in generic drugs, they risked their own safety. I think we have sent the message.

This is an Agency of 10,000 people, and I can't be monitoring every one of them, nor can I be monitoring any one of the hundreds of thousands of people involved in the industry and regulated products. Yes, there are going to be bad actors, but there is an Office of Criminal Investigations, there is an Office of Internal Affairs. They are very highly trained. There are 1,811 agents. I think that we have shown that we will take any misconduct on the part of anyone very seriously.

Mr. DEUTSCH. Could you follow up specifically with changes that you have made? Could you highlight anything that you have done?

Mr. KESSLER. There was no Office of Criminal Investigations before I got to the Agency. There was no Office of Internal Affairs. We were just in the process of establishing the Office of Ombudsman and Chief Mediator. The Office of Criminal Investigations and the Office of Internal Affairs are new.

Mr. DEUTSCH. Should the role of the HHS Inspector General in examining FDA matters be greater and should the FDA have its own inspector general?

Mr. KESSLER. I believe when we set up the Office of Internal Affairs and when we set up the Office of Criminal Investigations those were designed to work very collaboratively with the Office of the Inspector General. Everything that I have heard up to now leads me to believe that in fact that collaboration has been working.

Mr. DEUTSCH. Staff has mentioned the Office of Special Investigations. Could you elaborate on what that does and its history?

Mr. KESSLER. The Office of Special Investigations I also set up. They serve more as an early warning system. Employee misconduct activities go to Internal Affairs. The Office of Criminal Investigations deals with criminal conduct on the outside of the Agency. But if we are falling behind, if there is something that we should be doing that we are not doing—I know some on the committee expressed some concerns about inspections and whether we were doing our jobs—that office, for example, was involved in looking at that question and bringing that to our attention.

Mr. DEUTSCH. Let me focus on one of the cases that was raised in July, the Sensor Pad case. I've had the opportunity to look a little bit at the allegations involved. Specifically, is Sensor Pad on the market in Canada today?

Mr. KESSLER. Let me let Susan Alpert answer that question. She's the director of new device evaluation.

Ms. ALPERT. No, sir, it's not on the market in Canada at this point in time.

Mr. DEUTSCH. It was removed from the market in Canada?

Ms. ALPERT. The company was told that they could no longer market in, I believe, July 1994.