U.S. DEPARTMENT OF VETERANS AFFAIRS OVERSIGHT ON PATIENT SAFETY

HEARING

BEFORE THE

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HOUSE OF REPRESENTATIVES

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

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U.S. DEPARTMENT OF VETERANS AFFAIRS OVERSIGHT ON PATIENT SAFETY

THURSDAY, JUNE 15, 2006

U.S. House of Representatives,
Subcommittee on Oversight and Investigations,
Committee on Veterans' Affairs,
Washington, D.C.

The Subcommittee met, pursuant to notice, at 10:14 a.m., in Room 340, Cannon House Office Building, Hon. Mike Bilirakis [Chairman of the Subcommittee] presiding.

Present: Representatives Bilirakis, Boozman, Bradley, Reyes.

Also Present: Representative Nathan Deal.

Mr. Bilirakis. Good morning. Thank you all for being here as we discuss an important aspect of health care, and that is patient safety. Today we will discuss oversight of patient safety at Department of Veterans Affairs (VA) medical facilities.

This review of patient safety comes to us not only as part of the Subcommittee on Oversight and Investigations' agenda, but in the wake of problems identified at two VA facilities. Surgeons at the James Haley VA Medical Center in Tampa, Florida implanted an unsterilized cranial plate in a patient in February 2006, and nearly duplicated the mistake a week later. At another facility in Augusta, Maine, it was determined that a transrectal ultrasound transducer was improperly sterilized and cleaned, following medical procedures. It is my understanding that this incident was not a one-time occurrence, but happened repeatedly, repeatedly over a number of years, and that unclear instructions contributed to the sterilization problems.

Thankfully, we are unaware of any patients that were harmed in these incidents. These medical devices and other versions of them are used in VA facilities across the country. The VA had great difficult identifying the extent of the veteran patient population that may have been exposed to these inadequately sterilized devices.

Furthermore, VA was less than expeditious in notifying this exposed population. Since these medical devices are not unique to the

VA health care system, we have asked the Food and Drug Administration (FDA) to share with us what it has done to notify the entire U.S. healthcare delivery system of these patient safety implications, and we very much appreciate those good people being here.

Not only will we discuss the safety of medical devices that assist in patient care, but we will hear about the proper screening, or maybe I should say improper screening, possibly, of VA medical center employees, to include physician credentialing and privileging. In addition, we will review VA's policy and safeguards on hiring convicted sex offenders to work in the VA, and examine the implications for patient safety in VA employees.

Today, we will hear testimony from Dr. James Bagian, Director for the VA National Center for Patient Safety, who is here to discuss the situation of properly handling medical devices in VHA facilities. Dr. Bagian is accompanied by Dr. Lawrence Deyton, the Chief Public Health and Environmental Hazard Officer for the Veterans' Health Administration (VHA). From the Office of Inspector General (IG), Dr. John Daigh, Assistant Inspector General for Healthcare Inspections is here to share the IG findings on the medical device situations and on other patient safety issues found at VA medical centers. Additionally, Dr. Daniel Schultz, Director of the Center for Devices and Radiological Health at the FDA is here to share FDA procedures on approval of medical devices and how concerns are reported and handled. Finally, we have Laurie Ekstrand, Director of Health Care for the U.S. Government Accountability Office (GAO) -- it probably should be Dr. Laurie Ekstrand; is that correct?

DR. EKSTRAND. Yes sir.

MR. BILIRAKIS. I thought so -- to discuss the credentialing and privileging of medical professionals at VHA facilities.

I know we all look forward to hearing your testimony and answers to our questions, and I would now like to recognize my colleague, Mr. Reyes, for an opening statement.

[The statement of Mr. Bilirakis appears on p. 36.]

MR. REYES. Thank you, Mr. Chairman, and I apologize for keeping you waiting. We are here today reviewing patient safety issues in the VA, as a result of two recent problems that were observed and acted upon by watchful VA employees. In each of these events, a non-sterile device or implant was used medically on a veteran. And in each case, a VA employee asked questions and elevated their concerns until the true extent of the problem became clear and internal procedures were subsequently changed.

We all shudder at the thought of nonsterile invasive medical contacts. We all recognize that a host of complex medical procedures are performed by the VA on a daily basis, and that sometimes things will go wrong. Our goal is to help the VA find ways to reduce both the frequency and the severity of such problems. The events that we are

reviewing today did not result in physical harm to any veteran. We, collectively, learned something from analysis of these events. Had the VA observers remained silent, the problems might still exist, and might do harm to others.

As important as it is to analyze these problems, we must also assure that the oversight system that protects VHA patients remains vigilant and responsive. We must assure that patients outside VA are informed of potential problems with devices or with procedures. Where patient safety is involved, the pursuit of best practices will save many, many lives.

With that, Mr. Chairman, I yield back.

[The statement of Mr. Reyes appears on p. 37.]

MR. BILIRAKIS. The Chair thanks the gentleman. Mr. Boozman, for a brief opening statement? Mr. Bradley? All right, thank you.

It is only one panel, but this is a pretty darn hectic day for all of us. We very much appreciate your being here. I am going to figure on maybe giving you 10 minutes to present your statement if you would like. Of course, you can cut it down if you would like and allow more time for questions.

I would introduce Dr. Bagian -- I think I messed up your name a moment ago -- he is the VHA Chief Patient Safety Officer and Director of the VA National Center for Patient Safety with the Department of Veterans Affairs. Dr. Bagian, please proceed.

STATEMENT OF JAMES P. BAGIAN, M.D., PE, CHIEF PATIENT SAFETY OFFICER, DIRECTOR OF NATIONAL CENTER FOR PATIENT SAFETY, VETERANS HEALTH ADMINISTRATION, U.S. DEPARTMENT OF VETERANS AFFAIRS, ACCOMPANIED BY LAWRENCE R. DEYTON, MSPH, M.D., CHIEF PUBLIC HEALTH AND ENVIRONMENTAL HAZARDS OFFICER, VETERANS HEALTH ADMINISTRATION; JOHN D. DAIGH, JR., M.D., ASSISTANT INSPECTOR GENERAL FOR HEALTHCARE INSPECTIONS, OFFICE OF THE INSPECTOR GENERAL, U.S. DEPARTMENT OF VETERANS AFFAIRS; DANEL SCHULTZ, M.D., DIRECTOR, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND LAURIE E. EKSTRAND, DIRECTOR, HEALTH CARE, U.S. GOVERNMENT ACCOUNTABILITY OFFICE

STATEMENT OF DR. JAMES P. BAGIAN

DR. BAGIAN. Thank you, Mr. Chairman. It is a pleasure to be asked to talk to you today to explain what we do in the VA. As you know, I

have been before you before, and your colleagues, and we have been working for quite some time to really bring a culture of safety into the VA, where it is not strictly rules; it is to understand how people are willing, as was pointed out in the opening comments, willing to raise their hand when a problem occurs so we can address it in a systematic and effective way. That doesn't mean problems don't occur, but we are glad that we understand when they occur, because you can't fix what you don't know about. And we are glad that people are willing to come forward when they could have easily turned the other cheek and never told anybody, and then we would still have patients in peril.

I was asked specifically to speak about the issue in Tampa with the implant, and then the transducer, so I will discuss those first.

The issue with the implant in Tampa, the time line was basically as follows: February 28th, during surgery on a veteran where he had sustained injury from an IED, in OIF, they had to put an implant. It is a model of, like, a piece of the skull that they would put in place. And during the operation, the specimen was brought up, they opened it, went to put it in place, and having nothing to do with the implant, the condition of the patient was such that it would not fit. That was just because of swelling of the brain, something that can't be controlled.

They decided not to use the implant at that time, but in the process of doing this, one of the nurses who was alert became concerned. She said she thought she remembered that one of the pieces of paper -- and here is a replica of that -- that comes up with the implant is not sterile, and yet she found it on a back table. That is not the table right next to the operating table, but back there, and she said, " I don't think that's right."

She called the rep from the factory, you know, the factory rep, and she said, " Is this sterile or not?"

He got back to her and said, "No, the paper isn't sterile but the device itself is."

Subsequently, that didn't make sense to them. The following day on March 1st they said, " This doesn't really make sense that this could be that way," followed up more and found out that the representative from the company was in error, and in fact neither were sterile.

Now here is the thing I show you to understand how this happens. Here are two peel-back containers. They are commonly used in the operating room. If I asked you which one is a sterile and which one isn't, which one do you think is sterile? I will tell you one is in one is not. Which one would you say?

Mr. Reyes. I haven't been to Vegas in a while. I'd say the left one?

Dr. Bagian. This one is the sterile one? Okay.

MR. REYES. I don't know if it is my left or your left, too. You answer my question.

DR. BAGIAN. Well, okay, I will say it is my left. That is a good point. You are making my point anyway, that is even better.

Now if I turn them around, and now I ask you which one is sterile, still think this one?

MR. REYES. The white one.

DR. BAGIAN. Oh, now you are changing to this one. Okay. So now, this one. Okay, now it turns out this actually is the sterile one. However, they look identical. And the fact is --

MR. BILIRAKIS. I would say to the gentleman that is the one that I picked.

DR. BAGIAN. So now -- and it is good that you are lucky, because this nonsterile one looks like a sterile one, and there is almost no difference except there would be a little hourglass with a date there if it were sterile. That is the only difference. Now, when you look at things that come up in the OR, they come in peel-back. Usually, anything that comes in a peel-back is sterile. They handle thousands of times a day. What happens when this comes up to the operating room, this, with this on top of it, is there, sort of like when you buy aspirin and you open the box, you know that there is a label, that -- what do you do with that? You read that? You throw it away, right? Supposing this one you open today, in fine print it says, " If you take more than one, this particular new formulation, you will die." You would be in trouble I guess, right?

That is what this is like. When you get to the third page on this, in the fine print at the bottom, it says, " This is not sterile," when you get to this. Now let me show you, other people missed this as well. When you get this, the first thing it says about cleaning and sterilization, it says, " Do not autoclave." That is steam- sterilize, says " Do not do that." You know why? Because it will melt.

But interestingly enough, in the FDA's testimony, it says it was simply error, it says you should have sterilized it by steam. So they obviously had trouble reading this as well, preparing their testimony. But they still don't understand how it is supposed to be done. I guess other people can make errors, too. So the fact is this is a problem with the way this is set up. So even when the FDA got done, as you will see in their testimony, they say, " People should just read the directions."

That is not enough, because when you have a device that you supply thousands of times a day in this packaging, that is always sterile, and now send up one that is not, what do you expect people to do; to do what they have done thousands of times, or this one when it is in the throwaway paper that they get in every package? That is what happened.

So, we looked at the root cause. They did, too. They immediately

notified us, soon as they knew about it, that afternoon. They found out, they put it in our safety system, and they called us as well. We talked to them, within literally hours, we had called Stryker, who is the manufacturer of this, and talked to their -- sorry, it is not the vice president, but he is the -- in charge of regulatory affairs and risk management -- and talked to them -- regulatory affairs and quality assurance, I am sorry -- talked to him. He talked to us and said, " Can we talk more?" He came out and visited us. He said, " What can we do?" He said " There is a problem with this."

We said, "Why don't you label this on the thing itself, says, " not sterile" since it is in -- if you are going to keep it in the same packaging, it is in packaging that is routinely sterile, put " not sterile, must be sterilized," and not steam sterilized, because that is what most people do. It may not be steam sterilized. Ethylene oxide only. You know, there is even stuff you can put on the device itself so you do not have to worry about the packaging so when it is sterilized it goes away, so you could write on them with a drawing of a skull and crossbones, " not sterile," so that any surgeon who would get it would have it in front of them, and if it said " not sterile," they would know it. If it is sterilized, it goes away, you know, it disappears. We talked about it. That's all the things we said.

Nothing has happened with that. And as you can see, the recommendation from the FDA is, " Just follow the directions," which, while yes, it is written, but it is like reading the fine print in a contract; it is not really fair. We know in loan applications we don't allow people to do that.

So we went through that, and we are putting systems in place to get past that. You know, I know Dr. Daigh is going to talk to you, and we agree with the IG's report. We think the IG's report is accurate in virtually every respect. The way it happened is consistent with our root cause and showed the same things. We absolutely concur. Did somebody miss that it said sterilize that way? Absolutely, it is true. But it is more than that. You have to ask the second question, it is like Paul Harvey, " And now the rest of the story," that to have a better system is not just have systems in place, people, which can foul up, but make it easier for people not to foul up. And label them clearly to begin with.

So that is basically the sum and substance. As far as with the patients, we identified only two patients that had this happen, no others. I must admit that the ones that they used before this, the same kind of implant was made by another manufacturer, in the same packaging, looks the same, except it was sterile, okay. These are the first two times they ever used ones that were by this new manufacturer, labeled the same, except if you read the small print.

So that is kind of it for the Stryker. We go ahead then, then in end of January this year, you know, on safety walk-arounds. We

encourage our safety managers to walk, you know, look around their facilities for things that could be a problem, not wait for a problem to occur and then react, but in fact to go out and see what is going on. They were looking at scopes, and in the case of this transducer, it is a transducer that is introduced through the rectum to view the prostate, so you can do a biopsy just where you want to do it.

When they were there, they picked up one of the needle guides, it is a channel through which you put the needle that does the sampling, does the biopsy, and they held it up to the light and they couldn't see through it. They tapped it on the table, and some stuff fell out. Don't know what the stuff was, just some stuff. Obviously, it shouldn't be that way.

They immediately suspended all biopsy procedures in that facility while they looked at that. After they reviewed the situation and understood it, on February 13th, they instituted procedures again, and they notified us, and they said, " We think this is a generic problem with the way the instructions are written and carried out, and we think it could be a bigger problem."

So, we were notified on the 14th at 10:40. By 11:01, we had already had four other staff looking at all literature, talking to the factory and manufacturer. By a little bit later that day we had talked to Dr. Deyton, Dr. Roselle, we had talked to operations folks, we talked to our SPD, the people that do sterilization, those kind of things. That was all within hours of being known. Within less than a day, we sent out a note to all our sterilization SPD folks in the field, that they should have everybody review the procedures for their various devices, to make sure they are really complying with them the best they can. We sent a further clarifying message, to really point out about the brush, which was one of the issues, the following day.

So within less than 48 hours, we had gone out to all of our facilities. We also had the manufacturer, B-K Device, come in and talk to us, and they admitted that the directions can be somewhat problematic.

Oh, I forgot to mention, on the previous thing, I should have said this. On the previous device, Stryker, on March 6, after several days of knowing it, we filed with the FDA a Medwatch thing, a Medwatch report to the FDA reporting about the implant, and the recommendation was, they should be labeled, says " nonsterile" on the device itself, or on the packaging. That was in our suggestion to the FDA, but obviously they didn't think that was worthwhile.

Going back to this, we looked at our manuals, and I have these cross-tabbed, because you can't look at one manual to figure out how to sterilize it. It took over an hour and a half between three bioengineers, two of us who are also physicians, and a bioengineer that is just a bioengineer, to go through this to try to decipher what they really were telling us.

Now interestingly, I will tell you in November 2003 we found out

that this occurred in Toronto in nine hospitals, as well. And in the press, the open press, there are quotes from the medical officer there saying that the B-K device manuals are not clear. And this is reported in ECRI, as well.

So we went and looked through this. We worked with the company. The company actually was very good about working with us to make sure we could come up with a better, clearer procedure. During this time, we contacted the FDA as well, and we asked them some questions. After some time, they responded to us, after a little prodding, and responded to us about our alert, if they had any concerns. And they had some good questions that helped us clarify it further.

We then issued an alert on April 3rd to all VAs. Now, this is just in the first 48 hours, giving instructions. Now we had tested the real response, as far as going out to our facilities, piled them to make sure it really works. It is one thing to write a procedure; it is another thing to make sure it can be done appropriately. And that takes an iterative process; you can't do it in a day. We wanted to be thorough.

We did this. We worked at length with the facilities, with the company, who verified everything we put down, said, " Yes, that is correct," and we followed that up.

We completed that on April 3rd. That was completed, and since that time that has been out in the field. And that is basically what we have done to address it. We also, I should add, as with all our alerts virtually, we put them on the Web. Not just the internal Internet for the VA hospitals, but we put them so everyone else can look at them outside the VA, because we know that both inside the U.S. and outside the U.S., people subscribe to our web site because we often turn up things that haven't been written up by anybody else with very clear instructions; not just " Be worried," but " Here is what you can do to make it safer."

[The statement of Dr. Bagian appears on p. 38.]

MR. BILIRAKIS. Thank you, Doctor, I'm sure you weren't quite finished.

DR. BAGIAN. No, that is fine.

MR. BILIRAKIS. I did want to say that Chairman Nathan Deal, who chairs the Health Subcommittee on Energy and Commerce, which has full jurisdiction over FDA, has honored us by coming here today at my invitation.

Nathan, we should have notified you yesterday that we were going to have the FDA here, and I apologize for that. But --

MR. DEAL. Mr. Chairman, as you know, we have got a markup at 11:00.

MR. BILIRAKIS. I know.

MR. DEAL. I am going to have to leave, Mr. Chairman, but I appreciate your inviting me here. This is interesting testimony.

MR. BILIRAKIS. Well, and I want to skip Dr. Daigh if I may for a

moment, and skip right over to Dr. Schultz, so that we can hear from FDA while hopefully you are still here.

I also have to be at that markup, so I am not sure how we are going to get all this worked out, but Dr. Schultz, I would appreciate your summarizing your statement, if you would. You may have questions to ask, or points to make in rebuttal to what possibly Dr. Bagian said, I don't know. You have got 10 minutes, go ahead, sir.

DR. SCHULTZ. Thank you so much.

STATEMENT OF DR. DANIEL SCHULTZ

DR. SCHULTZ. I am Dan Schultz, Director of Center for devices and Radiological Health, at the Food and Drug Administration. I appreciate the opportunity to talk to you today about device safety and sterility, an issue --

MR. BILIRAKIS. Can everybody hear him all right? You might pull the mike a little closer, Doctor.

DR. SCHULTZ. Sorry. An issue that is of utmost importance to the agency. I have submitted written testimony for the record.

For my opening statement, I will provide a brief overview of our regulatory authority regarding medical devices, following which I will provide a discussion of the specific cases that brought us here today.

As defined by federal law, the term "medical device"encompasses several thousand health products, from simple articles such as tongue oppressors and heating pads, to cutting-edge and complex devices such as pacemakers, lasers, and imaging technologies.

The medical device amendments of 1976 gave FDA specific authority to regulate the safety and effectiveness of medical devices. The Federal Food, Drug, and Cosmetic Act prescribes a variety of mechanisms to achieve that goal. These include general controls, such as listing, registration, quality system requirements, prohibition of adulterated devices, premarket notification, record keeping, et cetera.

CDRH developed a medical device postmarket transformation initiative, which encompasses taking steps to increase its ability to identify, analyze, and act on postmarket information.

In 2005, the Center conducted a comprehensive inventory of its post market safety programs, including recalls, MDR reports, medical device safety network of about 350 hospitals and other facilities trained to recognize and report device-related adverse events.

We have prepared a report in ensuring the safety of marketed medical devices, CDRH's medical devices postmarket safety program, which documents the postmarket inventory, and discusses CDRH postmarket program.

A separate synopsis and recommendations document provides a

list of initial action steps the center will take to strengthen the effectiveness of our postmarket programs, and I would like to submit these for the record.

MR. BILIRAKIS. Without objection.

[The attachment appears on p. 52.]

DR. SCHULTZ. Thank you. As you know, FDA is in the process of addressing issues raised by the Department of Veterans' Affairs regarding the sterility of medical devices. We take these events very seriously, as they represent a serious breach in patient safety.

In the first case, the VA reported to FDA's Medwatch system an incident involving the potential implantation of a nonsterile cranial prosthesis into a patient at the James A. Haley Department of Veterans' Affairs Medical Center in Tampa, Florida.

A cranial implant, or cranioplasty device, is a device that is implanted into the skull to repair head injuries. Our manufacturer and user device experience database containing two reports from the device manufacturer, Stryker, one of which was linked to the VA report. The second report from Stryker described an incident apparently at the same VA facility, where a nonsterile cranioplasty device was actually implanted into a patient.

The manufacturer -- and I want to emphasize this -- the manufacturer characterized both of these adverse events as use error -- and I would like to talk a little bit about the difference between user error and use error, because we think that while the words are similar, there is a very important distinction and maybe I can get back to that later -- did not indicate that follow-up was warranted. Again, this was the manufacturer.

A search of the FDA adverse events database did not turn up any other reports of this nature for this type of device. There is no information in the adverse event database to indicate that the rate of infection associated with this type of device is abnormal, or is trending upward. And I would say that we look at about 180,000 adverse event reports per year, and one of the things that we try to do is not only look at the individual reports, but look at how those report fit together, and whether there are trends that would lead us in one direction or another. And again, I will get back to that later.

FDA conducted a report of the marketing application for this product and found that the device is nonsterile when shipped, consistent with industry practice for certain types of orthopedic and neurosurgical devices. The labeling states that the device should not be sterilized by steam sterilization, autoclaving, prior to use, and I will certainly go back and verify that because I understand that there is some question about the exact method that should be used for sterilizing this product.

But I think the bottom line is that this was a device for implantation, and I fully understand that there is some overlap in the sense

that some of these devices are provided sterile, where you just take it out of the package and it's ready for implantation, and some of these devices are provided nonsterile for the user to be able to manipulate, examine, do what they need to do with the device prior to implantation.

FDA concluded that the events were most likely attributed to use error -- and again I want to emphasize that word -- and that the adverse event database should be actively monitored for serious similar events. As with all reports of use error, FDA is looking for ways to reduce the likelihood that similar errors will occur.

In the other case, the VA informed CDRH staff that it had determined some of its hospitals were improperly cleaning and sterilizing reusable transrectal ultrasound transducer devices manufactured by B-K medical systems. The lumen of the needle guide was found to be soiled. Upon investigation, again, it was discovered that brushes were not being used to clean the lumen of the needle guide.

Transrectal ultrasound transducers are used to perform prostate biopsies. And I would emphasize that these types of devices are being used more and more, and it is because of these devices that patients with early prostate cancer can be identified, and can receive appropriate treatment. So when we talk about patient safety, which we obviously all believe is of paramount importance, we also have to talk about the availability of these life-saving diagnostic and therapeutic products.

FDA provided comments on the VA's draft patient safety alert, which VA subsequently issued April 3rd, 2006. FDA and the VA have been working together to ensure that users have clear and accurate instructions for cleaning and sterilizing the device.

In addition, FDA assembled a Post Market Action Team, what we abbreviate as a PMI action team, to investigate this matter and continues to work with the VA. The PMI action team is preparing a public-health notification to further reinforce for the user community recommendations of safe practices in reprocessing invasive ultrasound devices. The notification will focus on a broad range of reusable ultrasound transducers used for biopsy procedures. It will remind users of the importance of property cleaning and disinfecting these devices between uses, and reiterate how critical it is to comply with individual manufacturers' instructions for reprocessing the transducer assemblies. Because each brand and model of device may require different cleaning and sterilization procedures. The notification will automatically be forwarded to over 45,000 subscribers on our listserv, including health-care providers and hospitals.

For the incidents involving the cranioplasty devices, FDA has determined the events were attributable to use error, and the devices are labeled appropriately by the manufacturer. Thus, the Office of Surveillance and Biometrics will monitor the adverse event database

for any further reports, and if safety concerns arise, we will respond accordingly.

In addition, FDA is working on revising our labeling guidance for manufacturers, and will consider including recommendations that implantable devices supplied as nonsterile are clearly labeled as nonsterile.

With respect to the transrectal ultrasound transducer devices, the agency's actions will depend on the results of the investigation of the PMI action team. In addition, FDA will collaborate with the VA health care system to ensure delivery of safe and optimal health care.

We applaud the Veterans' Administration's proactive stance and their efforts to prevent further incidents involving these devices. We also appreciate the good work of the VA's office of Inspector General who investigated the nonsterile cranial prosthesis event, and whose conclusions and recommendations provide value for all of us. We will continue to work with the VA on both of these issues and take whatever corrective actions may be necessary to ensure the safety of medical devices.

And I just want to add, if I have two seconds left, we look at these kinds of reports as a critical piece of our postmarket surveillance process. We can't go out and actively survey all the uses of all the medical devices in this country. Systems, safety systems like the one at the VA, and other systems like our Medsun hospitals, provide us with these kinds of signals that allow us to look at these events, decide how widespread they are, how much they may indicate a wider problem, a wider concern, and take appropriate action. So we see this as a way of accessing information and being able to take appropriate action. And this is something that is critical to our process.

Thank you for your time, and I am happy to answer any questions you might have.

[The statement of Dr. Schultz appears on p. 44.]

MR. BILIRAKIS. Thank you very much, Dr. Schultz.

I am going to use the Chairman's prerogative here, and I have also gotten the approval of Mr. Reyes, to ask Mr. Deal to inquire, if you would like, Nathan. You know, the concern that I have and I think it is probably pretty obvious, first of all are the two departments or the two agencies coordinating adequately? But obviously the bottom line is also about patient safety. You have received a copy of this article in a Toronto newspaper back in 2003. 861 men were exposed to unsterilized equipment which was used in their particular case.

Well, go ahead, sir. Take all the time that you wish.

MR. DEAL. Thank you, Mr. Chairman, and thank you, Mr. Reyes, for affording me this opportunity, and I do appreciate the invitation, and I think it is important that Committees such as ours work together, because we have mutual interest and mutual concerns, and I

appreciate your reaching out in that regard.

I would just make first of all an observation. It appears to me that in the instance of the bandage that has been referred to here, it simply comes down to primarily a question of labeling of warnings. Now, that does not seem to be that complicated to me as an outside observer that there should be some standardization of warnings on the face of materials, such as has been suggested by Mr. Bagian, especially on materials such as this that are going into very sensitive portions of the body, the brain in particular.

And I guess that would be my first observation, is that why is there not some overarching requirement of labeling that is clear and unequivocal in these kinds of things? I don't think it is reasonable, even if the device is in the hands of a medical doctor, to expect them to wade through the minutia of a multipage small print instruction device. Why is that not an appropriate approach to solving that kind of problem?

DR. SCHULTZ. I think it is a fair question. All I can say is at this point, there is no specific requirement that a label be placed on a device clearly stating that it is a sterile or nonsterile, and I think this is something that we need to look at.

MR. DEAL. Does your agency have authority to put that in by regulation?

DR. SCHULTZ. Well, that is a good question. Actually, we have gone back and looked at our labeling regulation, and we may need some additional wording in the labeling regulation for medical devices that addresses that issue. And that is something that we will get back to --

MR. DEAL. I would appreciate if you would follow back up to both this Committee and my Subcommittee as well on the issue.

DR. SCHULTZ. You bet.

MR. BILIRAKIS. Will you do that within what kind of period of time here? I would like to put a time line on that. What is reasonable?

DR. SCHULTZ. In terms of following up on --

MR. BILIRAKIS. In terms of following up, communicating with the manufacturer, determining whether the regulations are adequate, whether that has to be changed, whether you need legislation or what the situation is there.

DR. SCHULTZ. The need for legislation may take a little bit of time. Could we say two weeks? Is that fair?

MR. BILIRAKIS. Two weeks you will notify us, as well as the Health Subcommittee on Energy and Commerce, thank you very much. Go ahead, sir.

MR. DEAL. Could I ask one other -- or make one other observation, followed by a question.

On the second issue, and that is the device that was not properly cleaned, sterilized, et cetera; my observation as a commonsense ap-

proach to that is, there are obviously some rather standardized disinfection devices, solutions, et cetera, that are commonly used for other devices, a variety of devices in a hospital setting. And I realize that every device may have its own peculiarities, such as the brush that has been referred to, et cetera. But can't there be some standardization of devices capable of being disinfected, for example, with the most common disinfectant solutions, procedures, et cetera, and not being allowed to be put on the market if they have some deviation from what would be a normal standard? Because I can just envision that if you are dealing with multiple devices, if it is like most of us, we can't remember what they said yesterday about this when you are putting another one in and it is different, and you have got all these little things taped to the wall, you know, about this device, you know, " Read this particular part of the instruction."

There seems to me, as a commonsense outside observer, that we ought to be approaching some kind of standardization of disinfection as a part and component of the approval of the device itself. Is that an unreasonable observation?

Dr. Schultz. I don't think it is unreasonable to try to achieve standardization in those areas that can be standardized. Again, the whole area of disinfection, it is not simply disinfecting, it is a matter of cleaning and making sure that all the gross material is not there, and then following up with either an appropriate sterilization or disinfection procedure. One of the things that we have noticed, and again, in looking at this incident, when we have gone back and looked at similar devices, and this is something that we have in fact recognized before, is that increasingly, as procedures go from being open, large procedures, to these minimally invasive procedures, which are in fact a good thing for patients, allow for diagnoses with minimal trauma; one of the, sort of, the byproduct of that is that companies are creating smaller devices that can be fit into smaller channels, which are more and more difficult to clean.

And I think again, what this points out, what this incident points out, is the need to pay more and more attention to those channels, and see if there is a way that we can in fact provide widespread standardized instructions on how to deal with those channels. So I think it is a fair comment.

Mr. Deal. Well, I am all in favor of small invasions.

Dr. Schultz. I understand. We all are.

Dr. Schultz. We are all getting to that age.

Mr. Deal. I would just like for us to try to make sure that we don't have these kind of complications, and it appears that maybe in light of the information that has now come forward on this issue, this might be a good springboard for looking at that approach. And I would be interested in hearing what conclusions you might reach in moving in that direction.

DR. SCHULTZ. Thank you.

MR. DEAL. And with that, Mr. Chairman, I will yield back the time you have so generously allowed me to have, and proceed to our hearing, and I will explain your absence or at least your delay.

MR. BILIRAKIS. Well, on community health centers, I would love to be there on that particular portion, as you know.

MR. DEAL. I understand.

MR. BILIRAKIS. So we will see. I was going to call on Dr. Ekstrand possibly while you are still here. I don't know, maybe you might have another five minutes or so?

Dr. Ekstrand, would you maybe proceed with your -- your written statement obviously is a part of the record, so if you would summarize, more than anything else.

STATEMENT OF LAURIE E. EKSTRAND

MS. EKSTRAND. Yes, sir, I have a brief summary.

I would like to thank you for inviting GAO to testify today concerning efforts by the Department of Veterans' Affairs to ensure that its health-care practitioners provide safe care to veterans. Specifically I would like to discuss findings related to patient safety in two reports that we are releasing today, and let me discuss the major findings of these two reports in turn.

First, more than two years ago we made four recommendations that were intended to close gaps in VA practitioner screening requirements for a wide range of employees that come into contact with veterans when they are provided health care. Today, we are reporting that although progress has been made in relation to all four areas, none of these recommendations have been completely implemented. For example, while VA has implemented procedures to verify that licenses and certificates held by those that VA intends to hire are completely verified, they have not extended this verification to include all licenses for those who are already employed with VA.

This means that a currently employed nurse, for example, could present a license to VA that is without restrictions, yet they have one or more additional licenses that are in fact restricted.

MR. BILIRAKIS. Doctor, forgive me. I know that I am being rude. While Mr. Deal is here, and take into consideration the jurisdiction over FDA, and I appreciate the fact that properly your report is regarding the VA Committee and the VA, here.

MS. EKSTRAND. Yes, sir.

MR. BILIRAKIS. Do you have, before you go into the rest of your -- do you have any comments regarding FDA, the relationship that exists or should exist between FDA and the Veterans' Administration, things of that nature that might be not only helpful to this Committee, but also helpful to the energy and commerce Committee?

MS. EKSTRAND. We have no specific work that addresses that, only commonsense.

MR. BILIRAKIS. Well, can we hear some of that commonsense.

MS. EKSTRAND. Common sense is that they should be talking to each other. But we have nothing specific --

MR. BILIRAKIS. Are they talking to each other?

MS. EKSTRAND. We have not done any work that would provide us any evidence one way or another, sir.

MR. BILIRAKIS. I see. Okay, well, all right, please continue. Apparently, she has no comments regarding the FDA. I wanted to let you go in case -- thank you, Doctor. Please continue, and again I apologize.

MS. EKSTRAND. Sure, no problem.

This review further documented that for the seven facilities we visited, compliance was poor with four of five screening requirements that we reviewed. Very briefly, in our report, we have a table that arrays seven facilities across the top, and five screening requirements down the side; thus we have a 35 cell table, and in each cell we either have a dark circle to signify compliance, or a light circle to show lack of compliance. Of the 35 cells, just 10 are dark to show compliance.

In our other report that we are releasing today, we have a somewhat more positive message concerning credentialing and privileging of physicians. Indeed, VA complied with all four credentialing and four of five privileging requirements that we reviewed. Let me outline our concern about the fifth privileging requirement --

To use information on physicians' performance in making privileging decisions -- that is the fifth requirement -- compliance with this requirement was problematic at six facilities because officials used information from their facilities' quality assurance program for privileging decision-making. Using this source of information is prohibited by VA policy, so as to preserve the confidentiality of quality assurance information.

We also raised concerns in this report about delays at three of seven facilities in submitting medical malpractice claim information to VA's office up medical legal affairs. This office reviews the information provided to make a determination as to whether substandard care has been provided. Delays in providing this information could lead to privileging decisions being made without the benefits of this information.

And finally, we report the need for internal controls to ensure that privileging information is accurate. In both of these reports I have talked about today we have made recommendations for further actions by VA, and VA has concurred with them. We believe that implementation of these recommendations is vital for patient safety.

Mr. Chairman, this closes my oral statement, and of course we would be happy to answer any questions you may ask.

[The statement of Ms. Ekstrand appears on p. 64.]

MR. BILIRAKIS. Thank you. Thank you very much, Doctor.

Dr. John Daigh is the Assistant Inspector General for Health Care Inspections for VA. Dr. Daigh, you are on, sir.

STATEMENT OF DR. JOHN D. DAIGH, JR.

DR. DAIGH. Thank you, sir, for the opportunity to testify this morning. I think I will just make a couple of comments in light of what has already been said.

First, I think that with respect to the issue at Tampa, and with the use of the medical devices at Togus, Maine and other places, I think that we, or my office, will work to try to seek standardization of the complex process by which supplies, equipment, and devices are procured and then work their way through the SBD system, up to the operating room. I think that is one level at which a VA can act relatively quickly to try to limit the chance that patients will be injured.

And then of course, the second level, as you have identified, is to work with agencies outside the VA, so that a prosthetic supply clerk doesn't have to make the decision at 150 different sites as to whether or not this particular bag is sterile or not sterile by just looking at the bag. It will be easier to arrive at the correct conclusions.

So I agree with the recommendations that the SPD to patient process needs to be reviewed. To the extent that we can require product design features to require standard sterilization procedures, safety will be improved. And as Dr. Bagian pointed out, big, bright visual cues to let you know whether a product is sterile or not would be important.

So I would have no further comment at this time, unless you have questions.

[The statement of Dr. Daigh appears on p. 55.]

MR. BILIRAKIS. Thank you, Doctor. Let me ask you first, Dr. Daigh, background checks. I know that there is only so much time here, and these other subjects, patient safety or directly related to patient safety is very significant. But what can you tell us about the background checks that the VA conducts?

DR. DAIGH. Well, sir, that is a little out of my area of expertise, but I will indicate that the IG's office has decided to not rely on the VA for background checks because they take so long to procure. So we, I believe, are investigating other methods outside the VA's current system to get background checks done. So there is dissatisfaction with the speed at which they occur. I am not able to comment more fully on that.

MR. BILIRAKIS. You have determined apparently, your office has determined that they take an unduly long period of time and therefore you have tried to come up with a different way to do it.

DR. DAIGH. That is correct, sir.

MR. BILIRAKIS. Why should that be? I mean, that is just as natural as anything can be. Shouldn't it be that we run background checks on people who are going to be servicing our veterans?

DR. DAIGH. Well, sir, I would have to respond to you in writing. I just am not an expert on background checks.

MR. BILIRAKIS. Do you have anything to add to that, Dr. Ekstrand?

MS. EKSTRAND. Yes, sir. We are reporting actually on page 11 of our testimony, we have a small table that indicates that in only one of the seven facilities we visited did we find that background checks were documented in employees' records to the extent that 90 percent of the ones we look at had the background checks in the records. It is difficult to tell from the records whether they were never completed, but we know that they were not recorded in the records.

MR. BILIRAKIS. Dr. Bagian, what impact would an inadequate background check have on patient safety? I know that has to concern you.

DR. BAGIAN. Well, one, I would say, you know, we don't run the background checks, and really I wasn't tasked to come forward and talk about that, so I really can't say much.

MR. BILIRAKIS. All right, but you can tell us your --

DR. BAGIAN. Certainly we would like to make sure we have people who are appropriately, you know, of right moral character, et cetera, et cetera, and that is why we do background checks. As to what the length of time is, I don't know how it is done, but I think it is not just done by us, there are other agencies that supply that service in the federal government. And I really don't know enough about it to comment about it effectively.

MR. BILIRAKIS. All right, but I have talked with you earlier and, you have testified before us previously. My feeling is that you are a very conscientious doctor here, and you care about patient safety and whatnot. So shouldn't it bother you that maybe there aren't adequate background checks taking place?

DR. BAGIAN. Well, certainly. I mean we would want to make sure that people have the appropriate checks as quickly as possible. But I guess I would also point out, as you do that there is always a risk assessment, you know, that I would say, that is how we look at all the safety things. You have to look at what the probability of a problem it is, and the severity of the outcome. You know, for example, hypothetically, suppose it takes five months to get a background check done. I think it is longer than that sometimes, depending on the level of background check that is required, and that depends on the position or the responsibilities of the individual involved. Suppose you need a cardiologist. You have no reason to believe through licensure and all of those things that was already mentioned, like in our VetPro, we know that they are licensed and all that, but the background check

isn't complete, and our choice is, would you like to have a cardiologist care for you, or nobody care for you, on the off chance that there is some mass murderer that you don't know about.

I mean, I think you have to make that judgment. And I think you really need to talk about the people that are running that program. And I really don't know enough to comment more than that. I think you have to look at what is the system demand versus the risk to the patient, and play that off against how fast you can get them qualified, and I really can't say more than that.

MR. BILIRAKIS. You know that we did have a mass murderer in the VA.

DR. BAGIAN. That was a long time ago, and that was before the VetPro, and that's why VetPro was put in, and I think which is what was, I'm not sure, but Dr. Ekstrand's comment about the licensure and that sort of thing. VetPro was put in place, which allows us to make sure that people have appropriate, you know, they are licensed, they really are licensed, that those source documents have been verified, that they really do have a doctor of medicine that is not from, you know, a cereal box or something like that.

So we have done that, which I would say there is virtually no other organization in this country that does that. And part of that was out of response of that one, and that particular mass murderer that you are talking about, I would point out that the VA is the one that discovered that one, and he had operated outside of the VA, where he had been responsible for the deaths of patients outside of VA. It was the VA that detected it. So while it is not a good thing, sir, you know, you only can do what you can do. And I agree we should do the best we can.

MR. BILIRAKIS. I should think that you would raise holy hell if you have the impression that proper background checks are not taking place in a timely fashion.

DR. BAGIAN. Well, I really haven't -- unfortunately, I haven't had a chance to review --

MR. BILIRAKIS. You can raise holy hell, I know that. That is why --

DR. BAGIAN. Well, that is true. I guess the first thing I would say is it is hard for me a comment in an intelligent way, because I have not had the opportunity to read Dr. Ekstrand's report. So I am not sure what is in it, to say if I should be. And when I read it, if there is reason, I certainly would do that.

MR. BILIRAKIS. If you need any help from this Committee and this Congress, you just let us know.

DR. BAGIAN. I am not bashful, you know that.

DR. BAGIAN. You are not bashful, right. Okay. We probably will go through a brief second round, but I just want to go ahead with Mr. Reyes at this point.

MR. REYES. Thank you, Mr. Chairman. And thank you all for your

testimony. I was curious, is there an industry standard in terms of checking into the credentials and the licenses, and all of those things? I mean, we have a government standard. Is there an industry standard by the American Medical Association, by the American Hospital Association?

DR. DAIGH. I don't think so, sir. We work by the VA policies, so there would be directives in policy that VA has, and when the Inspector General's office goes out, we look to see that that policy is reasonable, and that it is being complied with. I think the issue here is that the policy requires background checks, and they are not being done. And we consider that an important issue that needs to be addressed.

MR. REYES. Well, but in being able to make recommendations, isn't it a good idea to know what the civilian sector does, or how they, you know, because the potential for somebody either coming in with a false license, or somebody that has been -- I don't know, in the legal profession it is " disbarred," I don't know what it is called in the medical profession, but -- revocation of license, or whatever? Isn't that a good idea to --

MS. EKSTRAND. Sir, if I could add to this.

When a new employee is considered for being hired at the VA, there is a form that is filled out to determine what kind of background check might be appropriate for that employee. At minimum, there is a fingerprint-only background check, which means that the prospective employee's fingerprint is compared to the criminal history databases to determine whether there is basically a hit for this particular individual.

If it does in fact turn up something from the criminal history database, then it is up to the facility administration to determine whether this type of offense record is something that would not allow this person to work at VA.

But at minimum, there should be this fingerprint check. Some facilities were still installing the machinery to put this in place, but they seemed to be very close at the time we were finishing our work to having this functional, at all of the facilities.

MR. REYES. Dr. Bagian, given these concerns that have been raised, are you contemplating, or are you in a position to perhaps reevaluate, or make recommendations about what should be done, or what needs to be done in this area?

DR. BAGIAN. Well, I guess what I would do first is I would want to read the report and know what it says. Certainly after I read it, if it was showing material weaknesses, which I must assume that there are some material weaknesses there, certainly I will then ask, you know, the deputy undersecretary or the undersecretary, and say " It appears that there are weaknesses here. Why is that, and what does it take to make it right?" I mean, that would be my question. But that is about the most I can say without having the opportunity to

have read it.

MR. REYES. And I would give you a recent example, because a number of us on the Committee have been raising issues and concerns about the IT capabilities of the VA, funding studies and all that. The recent example of the release of 26 and a half million veterans' records is a very good example of these concerns not being taken seriously. Mine were compromised along with 26 million other veterans.

So I think it is vitally important that these concerns and these issues be taken seriously, and be given some kind of a deadline to be able to come back to the Committee and say, " Look, I have read the report. This is what the report says, this is where we are in terms of the issues raised by the report, and here is how we are going to get to where the report recommends that we be." Can I get your commitment to do that, in this area?

DR. BAGIAN. Well, I mean -- this, you know, the only commitment I can give you is within my scope of responsibility, and that is certainly I will read this report as pertains to safety and in general. I will make whatever comments seem appropriate after I read it to the principal deputy undersecretary, and the undersecretary, who is who I report immediately to. I guess that is all I can say.

I guess I would also point out, since you brought up the IT security thing, you know, the 26.5 million, 19 million, et cetera, I think one thing I would point out was, it wasn't a criminal act by one of our employees that caused that. It was the fact --

MR. REYES. Doctor, with all due respect, I mean, the results are the same regardless of whether it was willful intent, whether there was criminal --

DR. BAGIAN. Oh, there are problems, to be sure. And I assure you that the VA is taking that extremely seriously. I can't tell you, I cannot even begin to describe to you the efforts and time that has been spent as we have been I would say going back to basics on these security things, how much time is being consumed with that to make sure it is buttoned down. And I think that is appropriate, I do not disagree with that one little bit.

But I think the other thing we have to keep in the back of our minds, as we do this in a reasoned way, the goal is we don't want these things to happen, that is the goal. The goal is that we don't want to have somebody who is a criminal that is undetected or whatever, is of improper background to be delivering care. That is the goal, and the question is how do we get there? But I would still point out that that doesn't mean that there is no risk. You can have somebody that comes into the hospital that has all the background checks, and that day, they decide to do something weird, and --

MR. REYES. That is something I certainly would understand. But the reason I mentioned that breach was because for at least three to five years, and I have been on this Committee for 10 years, we have

been raising the issue of IT concerns and security to the Veterans' Administration funding a study, Mr. Chairman, if you recall, a study that largely was discounted by the VA, and they went off and did their own thing, and now we are seeing these kinds of consequences. So that is why I mentioned it.

And I think everybody on the Committee fully understands that we don't expect guarantees, but we do expect due diligence, especially in an area that is so vital to the health of our veterans, and the facilities that we operate.

DR. BAGIAN. Well, all I can say is I certainly don't disagree that we need to provide due diligence. I guess the other thing I would point out is everybody is working hard on the IT thing right now. I think there is no doubt if you talked to anybody, I don't care if they are at my level or if they are sweeping the floor, if they touch a computer they know there is something going on, there is no question.

I think the other thing I would point out is that where the problem occurred was not in the health system, it was not with medical records or anything like that, because our systems are a little bit better than were used on the other side. I mean just to be quite honest, you know, I am on the health side and they are different. We take it very seriously because we think patient records just by themselves are a huge responsibility, and we take it seriously. But that doesn't mean we shouldn't re-look at it, and we are.

MR. REYES. Thank you, Mr. Chairman.

MR. BILIRAKIS. The Chair thanks the gentleman, Dr. Boozman.

MR. BOOZMAN. Yes, thank you. We appreciate all of you being here. This really is an important topic.

Dr. Schultz, I think I would agree with Mr. Deal in the sense that it does make sense, these type of prostheses or devices that are put in really any place in the body, but certainly critical places, that it does make sense to make very clear if it is sterilized versus non-sterilized. That seems like it is common sense, and yet I understand in dealing with the agency, it is not as simple as it appears. And in order for you all to get things done, sometimes it is difficult. If we can be helpful in that regard, I think that would be an improvement.

On the other hand, Doctor -- Dr. Bagian --

DR. BAGIAN. That is all right. Bagian.

MR. BOOZMAN. Bagian. I am Boozman, Boseman, whatever.

DR. BAGIAN. I am the same way.

MR. BOOZMAN. If in fact some devices are shipped sterile, some aren't shipped sterile, it is the responsibility of the surgeon and his team to make sure that it is, regardless of the fine print or whatever, that is the bottom line.

DR. BAGIAN. Absolutely. Sure.

MR. BOOZMAN. And the other thing that I would say is that if you are having trouble with this particular product, I guess the question

is why continue to use it? Why not use one that is stamped like you would like it?

DR. BAGIAN. Well, we took action. I mean, as soon as we found out about it, we took action. It was within hours. So I mean, we found out it happened, we found out the one before that happened, they were within seven days of each other, that was how we found it out, and then we stopped it, then. Not three hours later, we stopped it then. So we did do that, and I think your recommendation is exactly appropriate.

MR. BOOZMAN. Right. On the other device that was used that wasn't sterile as we would like, was that at a hospital, or was that system-wide in the VA, or --

DR. BAGIAN. It is used in many places in the VA, but not the majority, but it is quite commonly used. That device is used in about 20 of -- it was used in 60 facilities of about 150 that could use it. Sixty used that device, and we represent, what was it, like 10 percent of the number of facilities in the United States -- not in the VA, but in the United States -- so we are just the tip of the iceberg that were --

MR. BOOZMAN. And those 10 percent that were using it were all of them doing it wrong?

DR. BAGIAN. About a third, right? About a third. Twenty-one of about 60 were not doing it exactly as they should.

MR. BOOZMAN. How about in private practice? What is the --

DR. BAGIAN. Well, I guess by talking to different people, I mean I have talked to people on the outside, and they said, " Oh, yeah, we have had those problems." So yeah, I know anecdotally from talking to directors in other hospital systems, and then as was pointed out, in a Sunnybrook in Toronto --

MR. BOOZMAN. I read the article. Yes, sir.

DR. BAGIAN. You know, it was at nine hospitals there, and I talked to their medical director there about that as soon as we turned it up, and he explained, " Oh yeah, we looked around." Every hospital that they had talked to in the Toronto area, nine hospitals, all had numerous patients that had that happen.

MR. BOOZMAN. I guess I would be curious, is that kind of what you are seeing, Dr. Schultz, also? I guess I would be concerned that if we had this problem in the VA and we weren't having it in Fayetteville, Arkansas in my local hospital and in Rogers, Arkansas, then I would have real problems with why the VA is lagging behind on this. If we were having problems throughout the country then that is another thing.

Go ahead, Dr. Schultz, if you would.

DR. SCHULTZ. I just wanted to say that I think that, you know, one of the concerns that has been raised is in terms of the time line in our response to this issue. And again, I think what you are raising is really sort of a critical issue to us, which is to figure out sort of what

the root cause of the problem is, and is it a particular facility, is it a particular product, or is it really something more generic?

And I think what we are all saying today is that in fact it is something more generic, that involves not a particular user or a particular product, but a range of products, and a new type of technology where we are starting to understand some of the unintended consequences of what is in fact a major advance in technology. This is not unusual. We have seen this problem in many other areas, going from infusion pumps to pacemakers, to a whole range of technologies, where as the technology changes, problems arise.

And again, the goal is to try to be able to understand what the problem is, and to try to be able to deal with it both thoughtfully as well as timely. And hopefully, our goal is to have a response out within the next few days that won't simply deal with this individual event, but will deal with the larger issue.

MR. BOOZMAN. Our patients that perhaps because of the sterilization technique wasn't as good as we would like, how are we doing as far as contacting them?

DR. BAGIAN. Let me refer that to Dr. Deyton, because he is running that whole part of the operation.

DR. DEYTON. Sure. Thank you for the question, sir. As Dr. Bagian said, of the 60 VA facilities that identified that they had ever used this particular set of equipment, 21 of them identified that the instructions for the way that they were reprocessing that equipment was not in the way that we later defined would be perfect. Those 21 facilities went back and looked at all of their records for when that device was used, and identified 22,122 patients who needed to be notified. And so we initiated a systemwide patient notification and look-back program to identify, those 22,000 patients, notify them and then tell them about the situation.

As of my last update of that patient notification program, 96 percent of those patients had been notified by their facilities. I am also pleased to report that there has been a vigorous response by those veterans to get more information about this. And 50 percent of those veterans who had been notified have already contacted their VA or the closest VA to get more information.

MR. BOOZMAN. Okay, good. Just one further comment, Mr. Chairman. It is good that the FDA and VA are here. It seems like with the VA being a closed system, the FDA in many cases, with certain areas, it looks like it would be good to talk to them, because I think with some things that you are wondering about, it does seem like with it being a closed system, a government agency, that it would be a good partner in dealing with some of these things. Does that make sense?

DR. SCHULTZ. I think it makes perfect sense, and in fact I think a lot of that communication does occur at the staff level. At least that is

my understanding of what occurs on a daily basis. I am not convinced that it occurs on an upper management level, but it certainly does occur on the staff level, and there have been a number of interactions on a number of different products with our staff and the VA staff.

MR. BOOZMAN. Okay. Thank you, Mr. Chairman.

MR. BILIRAKIS. The Chair thanks the gentleman.

Dr. Schultz, you may know that prior to this Congress, I chaired the Subcommittee that Mr. Deal chairs, I did that for 10 years. So I have spent a lot of time with the FDA, had the complete jurisdiction over it.

Well, I am an engineer, as well as a lawyer. I am more proud of the fact that I am an engineer. But I guess what I am saying is that, you know, it is important to get down to the bottom line on things. Mr. Reyes has talked, as did Mr. Boozman, about the privacy problems, and the mistake that was made, and we spent time on that. For years, we have talked about IT. We have had a roundtable in the other room with the VA, and nothing has -- nothing really has taken place so far as I can see. And they were warned by the IG, and by the General Accounting Office that there was inadequate security regarding IT in the VA, and just nothing of any consequence took place, and look at the problem that has developed.

Dr. Bagian, I do not want to put you in a difficult position here. But you heard Dr. Schultz testify, you have heard Dr. Daigh, Dr. Ekstrand comment. Do you have any comments regarding the relationship with FDA? You know, this Committee does not have any direct jurisdiction over FDA, I appreciate that and that is why I really am very appreciative of Dr. Schultz deciding to come here. I am not trying to put him or FDA in a difficult position, but I think it is important, indeed critical, that the problems that you all run into be coordinated with them, and that they pick up on it, because it involves incidents like unsterilized equipment used on 861 men for blood tests, which took place in Toronto. As a result, 861 men who received biopsies at the Toronto hospital between December in 1999 and August, 2003, have been told to get a blood test for hepatitis B or C, and HIV. I know there is something in here, that there are other hospitals who were using that same equipment, things of that nature. I would like to know, did VA pick up on this to see if the same problem had developed elsewhere in the VA? Did they pick up that they were going to try to do something about it? Has FDA picked up on that? Do you know, Dr. Schultz? This goes back maybe before your time, I don't know.

DR. SCHULTZ. I don't. I don't, but I will certainly look into that.

MR. BILIRAKIS. Don't you think that is important? I mean, isn't that the sort of thing that should concern FDA?

DR. SCHULTZ. Absolutely. I don't think there is anyone who would say that that shouldn't concern FDA. Yes.

MR. BILIRAKIS. So you don't really know what steps may have been taken by FDA at that time?

DR. SCHULTZ. I don't. I don't, but I will certainly find out.

DR. BAGIAN. I can answer that because I talked to the -- or whatever it is called.

MR. BILIRAKIS. Okay.

DR. BAGIAN. First, to answer your overall question: we have worked with the FDA ever since I have been -- I mean, I was the first director of patient safety in the VA, so I can tell you since the beginning we have often worked with FDA, especially at the staff level. And in general, the working relationship with the staff level people is generally very good.

Where we have had more problems, and I think this will be worked out. In fact, I want to point out right now that on the 27th of this month, from 2:00 to 4:00, there is going to be a meeting with the undersecretary, with Dr. Von Eschenbach, and I don't know who else he is going to bring from the FDA, to explore ways we can more productively interact, because we are concerned, as a result of this one right now, where I think it was this Committee, you sent a letter to the FDA, and we were copied, and also my boss, the undersecretary, sent a letter to Dr. Von Eschenbach as well, and we received no response for weeks. Even when I called Dr. Von Eschenbach's office, we received no response. And I was concerned because we wanted to work together and avoid a problem here, and we had problems with that. When we talked to them about this particular thing, you talked to the newspaper articles, we asked them about, do they look at ECRI, which is like the " consumer reports," and they said, " We don't usually monitor that," which we were kind of astounded at, that we even look at that, and this is reported in the ECRI in December of 2003, and they told us not just that they didn't know about it, but they don't see a reason to monitor ECRI, and that is what their expert team said, which we were kind of flabbergasted at.

We were the ones that approached FDA, not the other way around, that is the way it has historically been, including with this case and many others. In many cases, recently, when we have, we have received responses that, " Well, why don't you send us your alert when it comes out, but that is not really for us to worry about."

And that concerns us because we look at the goal a little differently maybe, as our responsibility is to make sure that the best thing happens for the patients. And my own opinion is that if the regulations or laws aren't right, you need to come forward and get them changed so they are right for the patient. And you know, the fact is that they might be a limitation today, but if you don't say anything about it, it doesn't get fixed. And that has been our concern all along.

So I think this is actually going to be a positive thing, what has happened today, because I think this is focusing everybody's atten-

tion on it, and I said before this hearing was rescheduled -- I mean, we had it back on the 25th, but before it was -- we actually had it canceled, you know, was three weeks ago, there was already the motion had been put in place that Dr. Perlin, the Undersecretary for Health, had already talked to Dr. Von Eschenbach about us having a meeting together to really improve the way we can help FDA really identify problems, and be more proactive. So we are all for that, and we look forward to the meeting at the end of the month, and in a couple weeks, that that will happen. So I think we are headed in the right direction.

MR. BILIRAKIS. All right. Before Dr. Schultz responds, I am reminded by staff that CDC published information last year stating that the ultrasound urology transducers can cause infection when not cleaned properly. FDA as I understand it did not know about that until we, meaning the Committee staff, told them. Comment, Dr. Schultz?

DR. SCHULTZ. I can't comment on that, but I will certainly find out about it.

MR. BILIRAKIS. Well, we are not getting very much information, here, and the reason I invited Mr. Deal here was because I don't know, I see a lack of cooperation here. You know, Dr. Schultz, I don't mean to put you on the spot and whatnot, but you are here representing FDA, and we are not getting answers. Mr. Reyes?

MR. REYES. Mr. Chairman, I was just notified that we expect a vote at 11:30, so maybe that will resolve the issue we were talking about.

But anyone that drives a car today, in their rearview mirrors, the one on the driver's side is a mirror that gives you the information as to what is coming up behind you without any reduction. On the right side, the mirror says on the bottom, " vehicles may be closer than shown," or I forget what the actual language is.

I was wondering, Dr. Schultz, when an issue like we discuss in terms of the sterile package and cleaning the instrument, when it comes up, first of all, do you have the authority, or what authority would you need to put out an immediate alert, and direct the manufacturer to put a notice, some kind of a transparent sticky notice on there, caution or alert, " Item not sterilized," or, " Refer to alert number such and such regarding the utilization of this instrument," something of an immediate nature that would preclude further hospitals or doctors from making the same mistake because the notice is on the third page, and very fine print, as Dr. Bagian notified; do you have that kind of authority, and would you be able to do that, to require the manufacturers to put out an immediate alert?

DR. SCHULTZ. We, if it were indicated, both we would have the authority to have the manufacturer do it, or we could do it ourselves. Again, I think the first thing that we do is try to understand the nature of the problem and the extent of the problem. I think one thing -- and I don't disagree that when you have a package that looks similar

for an unsterile and sterile product, that that is a concern, and it is something that we need to look at.

I would point out that in many of these cases, as far as I know, this particular item is somewhat unique in the sense that this particular company provides both a sterile and nonsterile model of the same product. As I said before, and as we talked about, there are many products that are provided nonsterile for sterilization by the user, and I think in most cases it is understood, and it is pretty apparent to the user that those products need to be then be sterilized at the user facility. There are other products that are uniformly provided sterile by the manufacturer, that don't require that kind of processing at the user facility. I do think that at least as far as I have been told, and as far as I know right now, it is unusual to have the same product provided both ways, which is probably why we have not seen this particular problem occur more extensively.

As I mentioned in my testimony this is certainly something that we want to look at, and if there is a particular issue with products -- again, you know, we want to provide the right size brush. If it is a narrow brush, to deal with particular products, we want to make sure we are doing that. If it is a broader brush, like the other item that we talked about, we want to make sure that we are doing that. And we will do that.

MR. REYES. Dr. Bagian, did you --

DR. BAGIAN. Well, I think, you know, certainly it is always a challenging thing if one looks like another. And I think the big issue here is understanding how prevalent the problem is, which I think is what Dr. Schultz was saying, and I think that is the issue, because the FDA is by reports, or self-reports. And self-reports are inherently inaccurate to give you the extent of the problem. Most things aren't reported at all; right? Wouldn't you agree, most things don't get reported? We know that statistically by observational tests, so the fact that you only have a couple doesn't mean that only a couple occurred.

For instance, in this particular case, had it not been for the diligence of the circulating nurse, that when she got an answer, even when she asked the factory rep and they said, " No, it is okay," and she looked at it and said, " That doesn't make sense then. Why would this piece of paper be nonsterile?" Didn't make sense, and she pursued it, and then not only pursued it, found out it wasn't true, and then had the courage -- and I think also, because of the culture that we created -- that she raised her hand and said, " You know, I think we screwed up."

You know, most places would not have asked the question, they would not have pursued it, and then when they found out they wouldn't have said, " we are going to tell the world," which is what we did, right, because they wouldn't want to come here. And we say,

" If that is what it is, we will stand up and take our hit because we are trying to help not just us, but anybody."

And I think that is one of the issues, when we say our reporting systems are not counting exercises, because you can't count. We say what they do is they identify a vulnerability, and it is for us to go out and see what is going on and say " What is the likelihood?" And if we know that is the case, we go and do something about it. And I think that is one of the differences in approach that needs to be used with these. And if you don't and only rely on self-reports to count, that you are missing the boat. You know, you won't know.

And we have shown many other cases where we have worked with the FDA, for instance with MRIs as a good example. MRI rooms, you know, where they do MRI, there are really strong magnets. And there are numerous cases where materials fly around the MR room, like whole IV pumps go catapulting across and hit the thing. We have pictures of floor buffers, IV poles -- not in the VA -- floor buffers, IV poles, shares, that are stuck in magnets. And yet, if you look at the reports, there are virtually none, very few, and yet they happen all the time.

And next time one of you goes to the MR room, if you happen to have an MRI, I just did a few weeks ago for a ruptured disc, I asked the tech, " Do many things fly around here?" because I noticed some of the marks on the gantry. And he goes, " Oh yeah, about once a month we have some things fly through here." And yet there is none reported because the techs just say, " that is just what happens." Whereas, we looked at it and said it, " That is a dangerous thing because people can be killed." As you might remember, a few years ago a boy was killed, a 10-year-old boy was killed in New York -- not in a VA hospital -- where an oxygen tank hit him in the head. And we said there is things you can do to design your system to do it.

It takes that proactive approach to understand where the risk is, and mitigate it before you have bodies stacking up like cordwood, and I think that is the kind of thing we look forward to collaborating with the FDA about, to try to share some of these ways to really identify problems before there is huge human suffering.

Mr. Reyes. Thanks. The other question that I had, Dr. Schultz, when you approve the product, do you also approve the literature that goes with it? For instance, the multipage document that gives the directions and cautions and all those, do you approve both?

Dr. Schultz. I wish I could give you a simple answer to that question. Unfortunately, it is not simple. As I mentioned in my opening statement, we have devices at various different risk levels and various different regulatory oversight levels, depending on risk. And there are certain devices that we look at extremely carefully, like a new heart valve, or a drug-coated stent, or some of the more novel high-risk devices, where we actually do go over the labeling and every

aspect of the testing, essentially word for word, and dot the " I's" and cross the " T's."

In the area of the products that are being discussed here, which are class two devices, one level below that highest level, we do look at labeling, but we don't look at it in the same way that we do for those higher risk devices. We look at it more generically to make sure that it meets, that it provides certain key aspects and meets certain standards, in terms of the kind of information that is provided.

So for instance, in the case of a device that requires sterilization by the user, a reusable device or an implant that would require sterilization, we would look at that product and look at the labeling, to make sure that it did in fact have instructions about how that device needed to be sterilized. But would we go back and forth and try to fine- tune it to the extent that we could ensure that every single user would understand that particular label? I think the fair answer that question is " no." And we depend on, again -- I apologize. I will stop.

MR. REYES. Well, the point I wanted to make is that there should be a threshold of reasonableness here.

DR. SCHULTZ. Right.

MR. REYES. To have the warning on the third page and in very fine print that, " Oh, by the way, this instrument is not sterile," is not -- I mean, I'm not asking that we guarantee that the instructions or the warnings be at a minimum third grade level or sixth grade level or whatever so that we minimize the understanding part of it. I think there is a greater concern, and this is predicated based on my own experience.

I had knee surgery in February. One of the forms that I signed was that I understood that an infection, a staph infection or some other type of infection could occur because of the surgery. And my daughter and my wife were with me, and my daughter asked the doctor, says, " Well, you know, we know that there is a possibility of infection even when you cut yourself, but why is this form particularly important?"

And I thought the doctor's answer was pretty germane, given what we are talking about here, is because there may be some instances where the instruments or some of the things that they use inadvertently may not be -- and I forget what the word that he used was, my daughter asked him, " Well, what does that mean?"

He says, "Well, something couldn't be sterilized, or even though we break it out of the sealed container, there could be some defect or something." Which, you know, I am willing to accept that as -- and I think the doctor said, " It is one in 10 million that it would ever happen, but we are required for liability purposes to do this."

So I would understand that. But I don't understand, knowing that this instrument is going to be -- I mean, what other use could possibly be put this instrument, other than implantation in a human being? So it seems to me like the assumption is sterilization is pretty darned

important. And we shouldn't require the warning, or we shouldn't expect for the warning to be way down the third page, in fine print. It should be prominently displayed so that people understand, " You are going to cut a human being open, you are going to clean out whatever is in there, you are going to insert this instrument, please make sure that this instrument is sterilized."

The other thing that concerns me is the issue of one of you says that whatever is boiling or steaming, I forget what the term was, is the way to sterilize it; but the other one says, " No, it is not the way" --

DR. BAGIAN. It is absolutely not. I mean, we --

MR. REYES. But either way it is a concern, because we have got two doctors that have a different opinion on something that should be a foregone conclusion.

DR. BAGIAN. Well, it is a Stryker label and I have it right here.

DR. SCHULTZ. I am not saying I have a different opinion. What I need to do is go back and look at the instructions. I am not saying that I have a -- that I am arguing about whether it should be sterilized this way or that way. I would have to go back and look at the instructions.

MR. REYES. Well, somebody should have vetted your testimony and said, " Oh, by the way, Dr. Schultz, this is" --

DR. SCHULTZ. Fair statement.

DR. BAGIAN. May I say something --

MR. REYES. That concerns me.

DR. BAGIAN. If I may say, I think this is just emblematic, I think it makes a great point that smart people looked at this. You know they didn't take it lightly preparing the testimony. But because this is so unusual, it is so unusual to say, " Don't autoclave," because that is how we usually sterilize everything, especially for implantation, but not with this device. And most are already sterilized, but not with this particular manufacturer's device. When they read it, the first thing that it says, " Don't autoclave," which is the same as steam sterilization, " Don't autoclave," because the thing melts. It basically shrinks and doesn't fit. It is only the third bullet that says, you know, you have to use ethylene oxide.

And when somebody read it, because it is what they call confirmation bias in human factors engineering; you see what you expect to see. That is how magicians work, right, the way a magician works is by, you see what you expected to see while they are doing something else. So here, very smart, very diligent people looked at that, and they put the exact wrong thing in. And if somebody followed that and they were putting the implant in my brain, they would get to do it, and they would say, " Wait a minute, it is 40 percent too small now, it doesn't work."

That would be, like, a bad thing.

But my point is, that is why just relying on reading that little in-

struction, even if they read it, is not the way to do it, and this just, like, proves the point that here, even the FDA doing it, didn't get it right. And that could happen to anybody else. And had I not been looking at this because of the problem, the way we did, I very likely would have read it just the way they did. And that is my point. It is not that they are not smart, it is not that they are not dedicated, that is not the issue at all. It is that they are human, just like we are human, just like the people down there are human, just like the representative for Stryker get it wrong initially, because it was so atypical.

I mean, I was -- shall we do the experiment, and show you what that means? I mean, let me just show you what this means. If I ask you right now if you want to try a little experiment to show you what this is about, if you put your hand on the table, if you want to play with me here. And every time I say " up," I want you to raise your palm and put it down as fast as you can. So I am going to go " up," and you are going to do that. Would you play with me here for, like, 10 seconds? You ready?

MR. REYES. You too, Chairman.

DR. BAGIAN. Ready? Just try this, anybody here try it, it will be an interesting experiment. Ready? Up. Up. Up.

Wait a minute, guys, I didn't say "up." My instruction was when I say " up." Was that so hard?

The point is, we could do that all day, and now you, knowing what I am going to do, and you still can't stop it. And if we put an EMG, a thing that measures when your muscles are going to contract, it still would spike because the way we are made is, when we associate pairs of things together, at all time, and when the exception occurs your brain can't handle it, because it is already wired for it. And that is what happened here.

MR. REYES. But Doctor, why, in another industry, there is a very simple rule. The Carpenter says, " Measure twice, cut once." And they are not dealing with human beings, they are not dealing with staph infections, all these other things. I mean, it seems to me like in the medical profession, we ought to have at least the minimum standards that a carpenter has.

DR. BAGIAN. Well, I think things are progressing. I mean, you know, I am an engineer originally, who happens to be a physician. And I think in engineering, or if you are a carpenter, these things make sense. But we don't train physicians or most health-care professionals in systems engineering practices and human factors engineering, and I think we now, only since 1999 or so, have we been progressing to talk about how systems are designed to do those very things.

And I think we are at the beginning, I think health care is advancing much more rapidly than aviation did, as an example, over time, because we are building on what has been learned by the carpenter,

by engineers, by others that say there are certain things you can do to systematize it, rather than be, " I am just smart enough to do it." It is not that you are smart enough, it has nothing to do with how smart you are. It has to do with good practice, and I think we are building those in, and I think that is what the FDA is working on, as well.

MR. REYES. Mr. Chairman, if I could ask one last thing. Could we enter into the record the Stryker label and all of the issues that we have been discussing here?

MR. BILIRAKIS. By all means. Without objection, that will be okay.

[The exhibits appear on p. 86.]

MR. BILIRAKIS. Dr. Schultz, and then I am going to go to you, John, in a minute, are you in a position to carry back some of the results of this hearing, and to see that something is done about it?

DR. SCHULTZ. I certainly am.

MR. BILIRAKIS. You are going to do that for us, are you?

DR. SCHULTZ. Yes.

MR. BILIRAKIS. Dr. Boozman to inquire.

MR. BOOZMAN. I thank you all for coming. I guess the purpose of this is to make sure that we are doing the procedural things right. It is not surprising that the government -- I don't think it is surprising that the government has some illegal immigrants working for them someplace. It is surprising that they are working in very sensitive positions.

And so if that is the case, then I would just encourage you to really look at your personnel. That is something that I think that illustrates that we really do have to be very, very diligent with our personnel. And I think probably some of the systems that we have relied on in the past and had good faith in evidently are not working, as illustrated by that. But again, I appreciate all of your all's hard work, I really mean that. Thank you.

MR. BILIRAKIS. Dr. Daigh, are you familiar with the -- I will call it a problem, because it is a problem -- the Bay Pines in St. Petersburg, the sex offender situation? I am talking about a lack of background checks.

DR. DAIGH. Sir, that is mostly being handled by investigations, so I am aware that that is an issue, but I don't have any particular insight into that.

MR. BILIRAKIS. Somehow the reporter found out about it regarding one sex offender, and then I think the hospital admitted to two, and now there are three there, and so we know that there are three.

So you can't comment any further on that? Dr. Bagian, you can't comment on that? Dr. Ekstrand, can you comment on that?

MS. EKSTRAND. No, sir, we haven't done any work related to that.

MR. BILIRAKIS. Does the VA keep a list of sex offenders? Anybody know?

MS. EKSTRAND. Not as far as I know, and I think it is unlikely, be-

cause the individual records about background checks are kept in the individual facilities in the files of the employee.

MR. BILIRAKIS. The employee only?

MS. EKSTRAND. So it is not in a major database.

MR. BILIRAKIS. Wow. Should it be? Doesn't it make sense that it should be?

MS. EKSTRAND. I think it is hard to say. Perhaps there should be some record when they get a hit, you know, that is when they identify someone who has a criminal history that needs to be considered before someone gets hired. Most of the employees that are screened, no doubt, are not hits on these databases. So keeping a record of all of it might be more than is needed.

MR. BILIRAKIS. Well, but we understand, you know, depends on your source and whatnot, that anywhere up to half of sex offenders re-offend after treatment. Taking that into consideration, accepting it if you will, you would think that there would be a list kept. Again, we are talking about a lack of adequate background checks and that sort of thing, so it is --

You know, Mr. Reyes really went into it on IT. He has been a member of this Committee for 10 years I believe he said. I have been a member of it for 24 years. The frustrations that we have with the VA, the inefficiencies, and the lack of paying attention to good advice from their IGs, and from the GAO, and from, well, sometimes I like to think even the Congress partake some good advice. But it has just been terribly, terribly frustrating.

You know, and all of the legislation in the world, first of all, it can't cover everything, shouldn't cover everything. Second of all, the regulations are drawn up, and by the agencies and by the departments, and quite often any similarity between those relations and the intent of the legislation is purely coincidental.

I am greatly concerned. I feel a little better about it here today, but you know, I am greatly concerned. FDA should be cooperating with the VA, and I hope that they are, and I will be probably personally talking to Dr. Von Eschenbach not too long from now, and plan to bring it up to him.

Dr. Schultz, we depend upon you an awful lot, to a large degree here, and we have an awful lot of questions in writing that will be submitted to you, and we are requesting that you submit responses to those. Again, use this Committee, if there are things that you feel need to be done, and your particular department or your particular agency is just not looking into it adequately. Use this Committee.

Dr. Boozman has this one last question, and then we have about nine minutes left to make this vote. Go ahead, sir.

MR. BOOZMAN. I know we need to go, Mr. Chairman. I would like to know, though, and again you can send this over because we do need to go, but on the application form, I am sure we ask people if they

have been convicted of a felony. I guess I would like to know if these individuals wrote down that they had been convicted and then we hired them regardless, as them being sex offenders.

MR. BILIRAKIS. Can you get that information to us?

MR. BOOZMAN. And then also, if they hadn't, if they wrote down "no," then I guess my question then is why are we not firing them because they lied on the application?

MR. BILIRAKIS. Can you all respond to that, please?

DR. BAGIAN. Yes.

MR. BILIRAKIS. Thank you very much. I am not sure that we have gotten as much information as we had hoped to acquire at this hearing, but then of course time has been a factor, too. You have been helpful, there is no question about it, and again, we appreciate your taking time and trouble to be here. You are busy people. We depend upon you for so very much. Thank you.

This hearing is adjourned.

[Whereupon, at 11:44 a.m. the Subcommittee was adjourned.]

APPENDIX

The Honorable Michael Bilirakis
Subcommittee on Oversight and Investigations
June 15, 2006

Oversight Hearing on VA's Oversight on Patient Safety

Good morning, ladies and gentleman, and thank you for being here as we discuss an important aspect of healthcare: patient safety. Today, we will discuss oversight of patient safety at Department of Veterans Affairs' medical facilities. This review of patient safety comes to us, not only as part of the Subcommittee on Oversight and Investigations' agenda, but in the wake of problems identified at two VA facilities.

Surgeons at the James Haley VA Medical Center in Tampa, Florida, implanted an unsterilized cranial plate in a patient in February 2006 and nearly duplicated the mistake a week later. At another facility in Augusta, Maine, it was determined that a transrectal ultrasound transducer was improperly sterilized and cleaned following medical procedures. It is my understanding that this incident was not a one time occurrence but happened repeatedly over a number of years and that unclear instructions contributed to the sterilization problems.

Thankfully, we are unaware of any patients that were harmed in these incidents. These medical devices and other versions of them are used in VA facilities across the country. The VA had great difficulty identifying the extent of the veteran patient population that may have been exposed to these inadequately sterilized devices. Furthermore, the VA was less than expeditious in notifying this exposed population. Since these medical devices are not unique to the VA health care system, we have asked the Food and Drug Administration to share with us what it has done to notify the entire U.S. health care delivery system of these patient safety implications.

Not only will we discuss the safety of medical devices that assist in patient care, but we will hear about the proper screening of VA Medical Center employees, to include physician credentialing and privileging. In addition, we will review VA's policy and safeguards on hiring convicted sex offenders to work in the VA and examine the implications for patient safety and VA employees.

Today, we will hear testimony from Dr. James Bagian, Director for the VA National Center for Patient Safety who is here to discuss the situation of properly handling medical devices in VHA facilities. Dr. Bagian is accompanied by Dr. Lawrence Deyton (Day ton), the Chief Public Health & Environmental Hazards Officer for the Veterans Health Administration.

From the Office of Inspector General, Dr. John Daigh, Assistant Inspector General for Healthcare Inspections, is here to share the IG findings on the medical device situations and on other patient safety issues found at VA Medical Centers.

Additionally, Dr. Daniel Schultz, Director of the Center for Devices and Radiological Health at the Food and Drug Administration, is here to share FDA procedures on approval of medical devices and how concerns are reported and handled.

Finally, we have Laurie Ekstrand, Director of Health Care for the U.S. Government Accountability Office, to discuss the credentialing and privileging of medical professionals at VHA facilities.

OPENING STATEMENT OF HON. SYLVESTRE REYES (D-TX)
June 15, 2006

Mr. Chairman,

We are here today reviewing patient safety issues in VA as a result of two problems that were observed and acted upon by watchful VA employees. In each of these events, a non-sterile device or implant was used medically on a veteran. And, in each case, a VA employee asked questions and elevated their concerns until the true extent of the problem became clear and internal procedures were changed.

We all shudder at the thought of non-sterile invasive medical contacts. We all recognize that a host of complex medical procedures are performed by the VA on a daily basis and that sometimes things will go wrong. Our goal is to help the VA find ways to reduce both the frequency and the severity of such problems.

The events we are reviewing today did not result in physical harm to any veteran. We – collectively – learned something from analysis of these events. Had the VA observers remained silent, the problems might still exist and might do harm to others.

Statement of
James P. Bagian, MD, PE
Chief Patient Safety Officer
Director of National Center for Patient Safety
Veterans Health Administration
U.S. Department of Veterans Affairs
On VA Patient Safety Programs
Before the
Subcommittee on Oversight and Investigations
Committee on Veterans Affairs
U.S. House of Representatives

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Mr. Chairman and Members of the Committee, I am pleased to be here today to discuss the vitally important topic of patient safety and some particular initiatives that are currently underway.

Inadequate patient safety is a critical worldwide problem in healthcare. In the U.S., estimates of the lives lost due to factors related to patient safety exceed that of the lives lost due to motor vehicle accidents, breast cancer, or AIDS (IOM, To Err is Human, 1999). In order to reduce medical errors, programs must first identify the underlying causative factors so that they can be understood, and then implement effective preventive strategies. Unfortunately, most healthcare systems and regulators have not modified their tactics to focus on prevention.

The systemic problems that are associated with medical errors and close calls persist; namely the misguided belief that accountability systems and punishment are the primary and most effective means to achieve improvement in patient safety. While accountability systems play an important role in health care organizations, they cannot do all things. Albert Einstein once observed, "Insanity: doing the same thing over and over again and expecting different results." This is where we seem to currently find many individuals and organizations in their quest for patient safety improvement. Put another way – traditionally the healthcare system has punished providers without giving them the tools to improve patient safety.

In many healthcare systems, an over-reliance on punitive accountability systems remains a major stumbling block to improvement because it does not encourage identification of potential problems and provides disincentives for reporting improvement. This state of events is not peculiar to healthcare and has been encountered by other industries. Aviation recognized that further improvement in safety could not be achieved by putting in place yet another accountability system. Instead they introduced a system whose purpose was learning, whose goal was prevention not punishment, and most importantly was viewed as both

beneficial and non-punitive by the end-users or those from whom reports are sought. Today in medicine there is no dearth of accountability systems but there is a scarcity of systems that are viewed as beneficial non-punitive reporting systems.

To address these needs the VA developed and continues to implement an innovative systems approach to prevent harm to patients within VA's 156 medical centers. VA recognized that individual human behavior is seldom the sole reason for medical adverse events - adverse events are usually due to the complex interaction of known and unforeseen vulnerabilities in health care delivery. Innovations were necessary, since no one had ever instituted a comprehensive systems-oriented safety program for large medical organizations. VA combined lessons from industrial settings, such as aviation and nuclear power, with the theory and body of knowledge from human factors and safety engineering to fashion systems that would better contribute to prevention of unintended harm to patients. (Human factors engineering was cited by the To Err is Human report as the discipline most often overlooked by health care when designing safety systems.) VA's accomplishments in patient safety improvement have been widely recognized, starting with winning the "Innovations in American Government Award" in 2001.

VA implemented nationwide internal and external reporting systems that supplement the many accountability systems we already had. The new systems' sole purpose was for organizational learning and improvement that would lead to improved patient safety for our veterans. Said another way, the objective for reporting is to identify vulnerabilities that can then be mitigated, not to serve as a counting exercise, as counting in itself is of very little value. They were constructed to encourage maximal reporting of potential and actually occurring problems by non-punitive methods that would then be converted into corrective actions. This was essential because without the ability to identify system vulnerabilities and to analyze their root causes for common systematic problems, our ability to achieve meaningful and sustainable patient safety improvement is limited. We designed reporting systems that would identify adverse events that might be preventable now or in the future.

In addition, we implemented systems to identify, analyze, and most importantly correct situations or events that would have resulted in an adverse event if not for either luck or the quick action of a health care provider -- we call such events "close calls." We believe that "close calls" provide the best opportunity to learn and institute preventive strategies, as they will unmask system weaknesses before a patient is injured, thus enabling preventive actions to be taken before harm occurs. This emphasis on "close calls" has been employed by organizations outside of health care with great success. It has been said that experience is the best teacher; however, it is also the most expensive. In the case of medically related experience, that cost can be expressed in terms of tragic consequences that are paid by patients. Close calls enable us to learn and

institute preventive actions without first having to pay the costly tuition born of human tragedy. In addition, proactive patient safety 'walkarounds' are another method that facilities use to uncover system vulnerabilities so that corrective actions can be taken without first having to encounter an undesirable outcome.

Once system vulnerabilities are identified there is a need to have the tools and methods available by which meaningful corrective actions can be formulated and implemented. The VA developed, tested, and implemented a number of approaches that not only allowed systematic prioritization of vulnerabilities but also enabled the identification of the underlying root causes and contributing factors, as well as appropriate systems level solutions. These tools are designed for application by personnel at the local facility level since analysis and solutions that are generated at the front line generally have the most individual relevance and the biggest impact on the development of a culture of safety at the specific institution in question. These tools, which include the Safety Assessment Code, Root Cause Analysis (RCA) process, Triage Cards, and Healthcare Failure Mode and Effect Analysis, are used throughout the VA system and are being employed in health care systems throughout the U.S. and the world.

When the causes of an event are determined to have potentially wide-ranging and substantial impacts on patient safety, VA's National Center for Patient Safety (NCPS) develops and issues a Patient Safety Alert in concert with the Office of the Deputy Under Secretary for Operations and Management. Our alert process employs a formal, standardized, scoring and tracking system that considers such factors as detectability, severity, and probability of occurrence to determine whether a Patient Safety Alert is warranted. Alerts are written to be concise and effective. Each includes a problem statement, one or more required actions, and specifies whether feedback is required and to whom. A completion date and time is provided for all actions, and a point of contact for additional information is always included. The development and deployment of an alert is a resource-intensive process as it requires in-depth understanding of the problem, and a similar understanding of the standard process(es) that are impacted by the problem. Once a solution is potentially identified, numerous steps are taken to verify that the proposed solution will improve the overall state of safety for the patient. These steps include, but are not limited to, communication with front line VA staff, manufacturers, designers, regulators, and any other entity whose input we believe might materially improve the final alert.

Prior to issuance, extensive review and often field testing is required to identify implementation problems that could diminish the effectiveness of the alert. We routinely post Patient Safety Alerts on our internet site www.patientsafety.gov so that patients outside the VA can benefit from the identification and mitigation of vulnerabilities we have discovered and acted on. These alerts have been judged to have high utility both inside and outside the VA as demonstrated by the numerous entities inside and outside the U.S. who have applied the knowledge contained in our alerts in their own health care systems.

Many other patient safety initiatives have been undertaken by the VA. A few recent examples are as follows:

- Patient Safety Curriculum – Rather than just retrain health care workers as to appropriate patient safety practices, VA formulated and disseminated a patient safety curriculum that is in use in over 40 medical schools and 60 VA Medical Centers (VAMCs). Curriculum workshops and tools have also been shared with the Department of Defense and the Indian Health Service. This is an ongoing effort that continues to expand to additional sites where U.S. healthcare workers are educated or trained.
- Falls Injury Reduction – Falls are the number one cause of injury-related death for those over 65 years of age. Our Falls Collaborative documented that 31 facilities reported a 62% drop in major injuries from falls. This equated to a projected cost savings of $25,000 per facility per month. We have continued our efforts through a current Falls Project involving 65 facilities. In total, participating facilities reported a 44% decrease in the major injury rate for acute care settings and a 67% decrease in behavioral health settings. This freedom from injury translates into greater independence for our patients. We have shared our methods and results through a Falls Toolkit, available electronically in its entirety on our website and accessed by over 400 non-VA visitors every month.
- Medical Team Training – Communication failure has been identified as one of the primary contributing factors in nearly 80% of more than 7,000 Root Cause Analysis events reported to VA. Implementing Medical Team Training has improved surgical infection prevention, deep vein thrombosis prophylaxis, and intraoperative communication and teamwork.
- Ensuring Correct Surgery – The work underlying this Directive identified the factors that could contribute to incorrect surgery, such as wrong patient, wrong side, wrong site, wrong procedure, and wrong implant. This more expansive systems based approach was revolutionary to the healthcare field, showing that fewer than 50% of adverse events were simple left/right (wrong side) mistakes and indicating that focusing solely on the side would not solve this problem. The approaches and techniques outlined in the Directive set the foundation for what was adopted on a national basis and have been employed internationally as well.
- Hand Hygiene – Improper hand hygiene has been implicated in a large percentage of hospital acquired infections that can have severe or catastrophic effects on the patient. Nationally the compliance of health care workers with appropriate hand hygiene practices is typically reported at less than 40 percent. The VA aggressively attacked this problem and was able to identify and implement a number of interventions that raised the observed compliance rate with the Center for Disease Control (CDC) guidelines to 80 percent, and greatly increased the use of antimicrobial soaps and alcohol-based hand sanitizers.

Two recent incidents occurring at facilities in different areas of the country reinforced the successful implementation of these NCPS processes. The national uniformity of the processes and the inculcation of staff demonstrated VA's strong patient safety culture and that VA responds proactively to identified patient safety vulnerabilities. These incidents have been discussed in depth with the House Veterans Affairs Committee members and staff so that you would be informed if your constituents contacted your offices.

The first one of particular interest to this Subcommittee involved the use of non-sterile Stryker Custom Cranial Implants. This was reported by the Tampa VAMC to the National Center for Patient Safety (NCPS) on 3/2/06. NCPS staff called and spoke with the Manager of Regulatory Affairs and Quality Assurance at Stryker that same day. NCPS called the VAMC the same day and reported the outcome of the conversation with Stryker and in particular that this was not a widespread problem at VAMCs. The Tampa VAMC submitted a voluntary report to FDA's MEDWATCH program on 3/6/06 and received an e-mail confirming receipt on 3/8/06. A RCA was conducted by the facility. The VA Program Director for Supply, Processing, and Distribution (SPD) sent an e-mail to VAMCs to determine other facilities that use the Stryker implant and how they were sterilizing it. It was determined that only one other VA facility used the implant in question and that it had been properly sterilized.

NCPS met with the Manager of Regulatory Affairs and Quality Assurance at Stryker and discussed the suboptimal human factors design issues of the packaging of the implant that increased the probability that sterilization would not always be accomplished. NCPS informed the Stryker representative that the use of packaging that is typically used for sterile materials and which lacked prominent labeling as to its non-sterile status was hazardous, and strongly suggested that it should be corrected. Investigation of the event revealed that one veteran had a non-sterile cranial implant implanted and that the surgical field may have been contaminated by a non-sterile implant for one other veteran. To date, neither veteran has experienced any complications directly related to the events. Both veterans will be monitored to ensure that there are no delayed infections. The facility has implemented the corrective actions specified in their RCA. VA Office of Patient Care Services, which includes VA's Infectious Diseases and SPD programs, has formulated a national Directive so that appropriate measures to assure the sterility of implantable devices are instituted across the VA.

VA recognizes that device labeling can be sub-optimal and we also realize our role in ensuring that equipment is safe for use. VA's Supply, Processing and Distribution Operations has taken aggressive action to evaluate the department's overall performance and effectiveness. In addition, an ongoing education is occurring throughout the VA that will equip staff to properly assess equipment readiness.

The other event that attracted interest concerns the appropriate processing of B-K Medical Urology Ultrasound Transducers and their accessories. These devices are used for ultrasonic viewing of the prostate, as well as for biopsy of the prostate under ultrasonic guidance. On 2/14/06 a memo was sent by e-mail to NCPS from the VAMC Director in Togus, Maine reporting a problem with the disinfection and cleaning of a B-K Urology Ultrasound Transducer that had been detected during patient safety rounds. The same day NCPS staff spoke with staff at Togus, received additional information, and informed the top VA officials for Public Health, Infectious Diseases, and SPD. The very next day B-K Medical provided NCPS with their General Transducer and Model 8808 Transducer User Guides, and there was a follow-up conference call.

The Director of SPD sent an e-mail to all SPD chiefs at VAMCs reminding them to refer to the appropriate VA Handbook regarding device processing, and the following morning he provided further instructions regarding B-K Medical Urology Ultrasound Transducers in particular. Upon thorough review of the B-K Medical User Guides, it became clear to NCPS and other VA staff that the instructions concerning the cleaning and processing of the B-K devices were extremely confusing and that this could contribute to the improper processing of these devices and their accessories.

B-K Medical requested that NCPS help with advice as to how to make the processing instructions clearer and a B-K Medical representative brought the transducer assemblies to NCPS for demonstration. To obtain additional information, the Director of SPD and a representative from the Office of the National Director for Infectious Diseases made a site visit to Togus VAMC. NCPS staff contacted CDC and FDA and both agencies responded with feedback on a draft of VA's Patient Safety Alert.

All aspects of the alert were also reviewed by B-K Medical and endorsed as correct for implementation and then tested at a variety of field settings to determine usability by VAMCs prior to its release. On 4/3/06, VA issued a Patient Safety Alert to VAMCs describing the procedures for appropriate processing of B-K Medical Urology Ultrasound Transducers (models 8808 and 8551). The final alert was shared with the CDC and FDA, and subsequently with our colleagues at the Department of Defense.

Thank you for the opportunity to present this information to the Committee. I will be happy to respond to any questions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT OF

DANIEL SCHULTZ, M.D., DIRECTOR

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
FOOD AND DRUG ADMINISTRATION
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
COMMITTEE ON VETERANS AFFAIRS
HOUSE OF REPRESENTATIVES

JUNE 15, 2006

FOR RELEASE ONLY UPON DELIVERY

INTRODUCTION

Mr. Chairman and Members of the Committee, I am Dr. Daniel Schultz, Director, Center for Devices and Radiological Health (CDRH) at the Food and Drug Administration (FDA or the Agency). I consider device safety and sterility to be of utmost importance and appreciate your invitation and the opportunity to discuss this issue.

BACKGROUND

Let me begin with a brief overview of our regulatory authorities regarding medical devices. As defined by Federal law, the term "medical device" encompasses several thousand health products, from simple articles such as tongue depressors and heating pads, to cutting-edge and complex devices such as pacemakers, lasers, and imaging technologies.

The Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic (FD&C) Act gave FDA specific authority to regulate the safety and effectiveness of medical devices. The FD&C Act prescribes a variety of mechanisms to achieve this goal. These include our general controls: quality system requirements for manufacturing; prohibition against adulterated or misbranded devices; pre-market notification (510[k]) requirements; the ability to ban device types; registration of manufacturing facilities; listing of device types; and record keeping, repair, replacement and refund.

Devices on the market at the time the 1976 Amendments passed, were assigned to one of three "classes." Devices posing the lowest risk, such as elastic bandages, were placed in Class I, subject to the "general controls" I just outlined. Class II devices, such as laparoscopes and powered wheelchairs, which pose incrementally greater risk and whose safety and effectiveness cannot be adequately controlled solely with Class I requirements, are subject to "special controls." These special controls include guidance documents, patient registries, post-market surveillance studies, and mandatory performance standards. The riskiest devices, such as some implants and life-supporting or life-sustaining devices, are placed in Class III. Class III devices undergo pre-market evaluation, including clinical studies, and must be found to be safe and effective for their intended use before manufacturers can introduce them into commerce.

MEDICAL DEVICE POSTMARKET TRANSFORMATION INITIATIVE

FDA's post-market programs for medical device safety include recalls, the Medical Device Reporting Program, and the Medical Device Safety Network of 300 hospitals and other facilities trained to recognize and report device-related adverse events.

As part of the Center's Medical Device Post-market Transformation Initiative, CDRH is currently working to increase its ability to identify, analyze, and act on post-market information in order to improve the safety and effectiveness of medical devices and radiation-emitting products. In 2005, the Center conducted a comprehensive inventory of its post-market safety programs, looking at successes and challenges in implementing effective programs.

The post-market safety program inventory considered:

- how we identify post-market problems;
- how we assess the information we obtain; and
- how we respond to that information through both stakeholder communication and enforcement action.

The Center's plan to strengthen its post-market program focuses on:

- developing a "culture of collaboration" for post-market safety within the Center;
- developing world-class data sources and systems to quickly and accurately collect, analyze, and disseminate information about potential risks;
- enhancing risk communication efforts; and
- improving coordination with the FDA field staff.

A senior-level team, comprised of CDRH management and outside consultants experienced in medical device safety and product regulation, will help guide the Center in this effort. This team plans to complete its work this summer.

CDRH has prepared a report, "Ensuring the Safety of Marketed Medical Devices: CDRH's Medical Device Post-market Safety Program," which documents the post-market inventory and discusses the CDRH post-market program. A separate Synopsis and Recommendations document provides a list of initial action steps the Center will take to strengthen post-market effectiveness. We would like to submit these items for the record.

STERILITY ISSUES RAISED BY THE DEPARTMENT OF VETERANS AFFAIRS

As you know, FDA is in the process of addressing issues raised by the Department of Veterans Affairs (VA) regarding sterility of medical devices. We take these events very seriously, as they represent a serious breach in patient safety.

In the first case, the VA reported to FDA's MedWatch System an incident involving the potential implantation of a non-sterile cranial prosthesis into a patient at the James A. Haley Department of Veterans Affairs Medical Center in Tampa, Florida. A cranial implant, or cranioplasty device, is a Class II device that is implanted into the skull to repair head injuries. Our Manufacturer and User Device Experience database contained two reports from the device manufacturer, Stryker Leibinger, one of which was linked to the VA report. The second report from Stryker described an incident, apparently at the same VA facility, in which a non-sterile cranioplasty device was actually implanted into a patient. The manufacturer characterized both of these adverse events as "Use Error" and did not indicate that further follow-up was warranted. A search of the FDA adverse events database did not turn up any other reports of this nature for this type of device. There is no information in the adverse events database to indicate that the rate of infection associated with this type of device is abnormal or is trending upward. FDA conducted a review of the device labeling for this product and found that the device is non-sterile when it is shipped, consistent with industry practice. The labeling states that the device should be "sterilized by steam sterilization (autoclaving)" prior to use. FDA's Office of Surveillance and Biometrics (OSB) concluded that the events were attributable

to user error and that the adverse events database should be actively monitored for similar events.

In the other case, the VA informed CDRH staff that it had determined some of its hospitals were improperly cleaning and sterilizing reusable transrectal ultrasound transducer devices manufactured by B-K Medical Systems, Inc. Transrectal ultrasound transducers are Class II devices used to perform prostate biopsies. The lumen of a needle guide was found to be soiled. Upon investigation, it was discovered that the brushes were not being used to clean the lumen of the needle guide. FDA provided comments on the VA's draft Patient Safety Alert, which the VA subsequently issued on April 3, 2006. FDA and the VA have been working together to ensure that users have clear and accurate instructions for cleaning and sterilizing the device.

In addition, FDA assembled a Post Market Issue (PMI) Action Team to investigate this matter. PMI Action Teams, staffed with appropriate clinical, scientific, technical, and regulatory expertise, are convened to develop recommendations for actions that will address public health issues. The PMI Action Team for this device is continuing to work with the VA. The PMI Action Team is preparing a Public Health Notification to further reinforce for the user community recommendations of safe practices in reprocessing invasive ultrasound devices. I am pleased to report a draft copy of the Public Health Notification is undergoing final review by both internal and external experts in this issue. We hope to post the Public Health Notification on its webpage within the next week. The Notification focuses on a broad range of reusable ultrasound transducers used for

biopsy procedures. It will remind users of the importance of properly cleaning and disinfecting these devices between patient uses and reiterate how critical it is to comply with individual manufacturer's instructions for reprocessing the transducer assemblies because each brand and model of device may require different cleaning and sterilization procedures. The Notification will automatically be forwarded to over 45,000 subscribers on our list server. This will ensure that the message will be widely disseminated to healthcare providers and hospitals.

NEXT STEPS

For the incidents involving the cranioplasty devices, FDA has determined that the events were attributable to user error and the devices are labeled appropriately by the manufacturer. Thus, FDA will monitor the adverse events database for any further reports, and, if safety concerns arise, will respond accordingly. In addition, FDA is working on revising labeling guidance for manufacturers and will consider including recommendations that implantable devices supplied non-sterile are labeled "non-sterile."

With respect to the transrectal ultrasound transducer devices, the Agency's actions will depend upon the results of the investigation and analysis of the team of experts participating in the PMI Action Team. In addition, FDA will collaborate with the VA health care system to ensure the delivery of safe and optimal health care.

CONCLUSION

We applaud the VA's proactive stance and their efforts to prevent further incidents involving these devices. We also appreciate the good work of the VA's Office of Inspector General, who investigated the non-sterile cranial prosthesis event, and whose conclusions and recommendations provide value for us all. We will work with the VA on both of these issues and take whatever corrective actions may be necessary to ensure the safety of medical devices.

FDA Public Health Notification: Reprocessing of Reusable Ultrasound Transducer Assemblies Used for Biopsy Procedures

(You are encouraged to copy and distribute this information)

Issued: June 19, 2006

Dear Colleagues:
This is to alert you to the importance of properly cleaning and sterilizing reusable ultrasound biopsy transducer assemblies (i.e., transducer device and associated accessories), and to provide recommendations for doing so. If these devices are not correctly reprocessed between patients, residual material from a previous patient may contaminate the biopsy needle and needle guide when the system is reused for biopsies. This could lead to patient infections.

On April 3, 2006, the Department of Veterans Affairs (VA), Veterans Health Administration issued a Patient Safety Alert related to a particular company's ultrasound transducer assemblies. During patient safety rounds, the lumen of a needle guide of an ultrasound transducer assembly was found to be soiled. The alert provided recommendations on reprocessing that brand of transrectal ultrasound transducer, which is widely used throughout the VA. FDA is issuing this notification as a supplement to the VA alert because we believe inadequate reprocessing procedures may be a problem for all invasive ultrasound transducer assemblies.

Background

Health care professionals use ultrasound transducer assemblies to view body structures and obtain biopsy samples under ultrasonic guidance. To facilitate biopsy, these devices may have a needle guide attached that directs the insertion of a biopsy needle. The procedure often involves placing the transducer in a body cavity where contact with blood, other body fluids, or feces is likely. During this procedure, the transducer assembly should be covered with a sterile barrier sheath (e.g., a condom). It is important to follow the manufacturer's labeling with regard to the use of sterile covers for each particular device in order to reduce the risk of patient infection.

Insertion of the biopsy needle is often repeated through the guide. Since a biopsy needle contacts the needle guide before it penetrates sterile tissue for biopsy, the needle and needle guide should be reprocessed as *critical devices.* * The biopsy needle and its containing guide must **always** be sterilized. This should apply even if a sterile barrier sheath is used on the transducer assemblies during a biopsy procedure, as the sheath is compromised by the penetration of the needle.

* Critical devices require sterilization between patients unless they cannot withstand the rigors of sterilization. **In these cases only**, high level disinfection can suffice for the parts that cannot be sterilized. Definitions for critical device, semi-critical device, high-level disinfection, and sterilization available at: ANSI/AAMI ST58:2005, *Chemical Sterilization and High-Level Disinfection in Health Care Facilities.* http://www.aami.org].

The importance of cleaning

For any reprocessing method to be effective, **the reusable device must be thoroughly cleaned before it is subjected to the sterilization process**. Brushes should be used, when required, to effectively clean the transducer assemblies, especially the lumens. Failure to brush needle guide lumens has resulted in improper reprocessing, and may have been associated with the transmission of patient infections. We have received reports of visible residue in the biopsy needle-guide channels of some patient-ready reusable transducer assemblies.

If your transducer assembly kits are not supplied with brushes, ask the manufacturer for all relevant specifications for the appropriate brush and a source(s) for purchase of these brushes.

It is also essential to use appropriate detergents for cleaning and enzymatic cleaners for removing proteins from the transducer assemblies. Refer to the manufacturer's instructions for information on compatible detergents and cleaners.

Recommendations

In order to avoid reprocessing problems, it is critical that you follow the manufacturers' instructions for reprocessing these transducer assemblies. The operators manuals/user guides for these transducers should give detailed instructions for cleaning and sterilization for each specific brand and model of device, and specify the equipment and supplies needed to correctly reprocess the assemblies. These reprocessing instructions have been validated by the manufacturer. Sterilization processes that are recommended by the transducer manufacturer should be used. Steam sterilization or liquid chemical high level disinfection is to be used as recommended by the transducer assembly manufacturer. If there is anything in the manufacturer's instructions that is not clear, contact the manufacturer for clarity. Make no assumptions.

Remember, you can not achieve sterilization or high-level disinfection unless the assembly is cleaned first.

When cleaning and sterilizing re-usable ultrasound transducers, be sure to:

- Disassemble the transducer assembly parts for cleaning.
- Use a clean and properly-sized brush for each lumen of the device that is being cleaned.
- Thoroughly clean all surfaces of reusable components.
- Brush and thoroughly rinse the channels through which the biopsy needles pass and any areas where the needle guide passes through the transducer to loosen materials inside the lumens, and check to be sure that no visible soil remains.
- Thoroughly examine all surfaces that have been cleaned and visually inspect the ENTIRE device to make sure it is clean.
- Steam-sterilize all heat-stable, reusable components after each use. If using automatic reprocessing equipment, be sure to utilize the proper connections to the transducer assemblies.
- Use a liquid chemical high-level disinfectant ONLY for heat-sensitive components that cannot withstand steam sterilization. Be sure to flush any lumens or channels with the disinfectant to ensure that the disinfectant reaches all areas inside the lumens.
- **Always use sterile water for rinsing or removing residual germicides from devices which have been processed using liquid chemical germicides. Do not** rinse reprocessed devices with tap water, which may recontaminate the device.
- Thoroughly dry the device after rinsing with sterile water.
- Do not reuse or reprocess items labeled for single-use (e.g., single-use biopsy needles), which have not been validated for reprocessing.
- After sterilization, appropriately package and store the device or component to ensure that sterility is not compromised prior to reuse.

If you find that the manufacturer's reprocessing instructions seem to be inadequate, please inform the

manufacturer and MedWatch about those inadequacies.

Reporting to FDA

FDA requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices. If you suspect that a reportable adverse event was related to the use of an ultrasound transducer assembly, you should follow the reporting procedure established by your facility.

We also encourage you to report adverse events related to ultrasound transducers used for biopsy procedures that do not meet the requirements for mandatory reporting. You can report these directly to the device manufacturer. You can also report to MedWatch, the FDA's voluntary reporting program. You may submit reports to MedWatch by phone at 1-800-FDA-1088; by FAX at 1-800-FDA-0178; by mail to MedWatch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852-9787; or online at http://www.fda.gov/medwatch/report.htm.

Getting More Information

If you have questions about this notification, please contact the Office of Surveillance and Biometrics (HFZ-510), 1350 Piccard Drive, Rockville, Maryland, 20850, Fax at 240-276-3356, or by e-mail at ohann@cdrh.fda.gov. You may also leave a voice mail message at 240-276-3357 and we will return your call as soon as possible.

FDA medical device Public Health Notifications are available on the Internet at http://www.fda.gov/cdrh/safety.html. You can also be notified through e-mail each time a new Public Health Notification is added to our web page. To subscribe to this service, visit: http://service.govdelivery.com/service/subscribe.html?code=USFDACDRH_10.

Sincerely yours,

Daniel Schultz, MD
Director
Center for Devices and Radiological Health
Food and Drug Administration

Updated June 19, 2006

STATEMENT OF

DR. JOHN D. DAIGH JR., M.D.

ASSISTANT INSPECTOR GENERAL FOR HEALTHCARE INSPECTIONS

OFFICE OF THE INSPECTOR GENERAL, DEPARTMENT OF VETERANS AFFAIRS

BEFORE

THE SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

COMMITTEE ON VETERANS AFFAIRS

THE UNITED STATES HOUSE OF REPRESENTATIVES

ON

PATIENT SAFETY ISSUES AT THE DEPARTMENT OF VETERANS AFFAIRS

JUNE 15, 2006

INTRODUCTION

Mr. Chairman and Members of the Committee, thank you for the opportunity to testify today on patient safety issues that directly impact the quality of life of millions of veterans who receive their medical care from Department of Veterans Affairs (VA) medical facilities. Today I will present you with the results of the Office of Inspector General's (OIG) Combined Assessment Program (CAP) evaluations of Veterans Health Administration (VHA) medical centers, selected hotline evaluations, and national reviews that are relevant to the discussion of VHA patient safety issues.

I believe, from my personal experience and OIG work, that VHA leadership and employees are committed to provide veterans with the highest quality medical care. In addition, I am convinced that VHA leadership strongly supports patient safety to the betterment of all veterans. There is no better example of VA employees' commitment to veterans than the recognition received by the Portland VA Medical Center when they were recently named a nursing Magnet facility by the American Nurses Credentialing Center.

The OIG evaluates the quality of medical care provided to veterans through a variety of methods. The CAP review process is one in which VHA medical facilities are evaluated on a 3-year cycle. These reviews are designed to ensure that the processes are in place at each medical center to ensure that VHA leadership can effectively provide veterans with quality health care. A strong patient safety culture is one of the attributes of a well-managed medical facility. Rarely have we determined, in the course of our CAP inspections, that VHA facilities did not have the processes in place to ensure that quality medical care was likely to be provided and that a strong patient safety culture was not present. When we have found and reported these conditions, VHA has taken appropriate and timely actions to remedy the situation.

CAP reports describe areas where VHA needs to improve and highlight areas where standards are properly maintained. A summary of CAP quality assurance findings representing evaluations of 93 VHA medical centers for FY 2004 and FY 2005 provides the basis for the conclusion that VHA leaders and employees support the processes and procedures that are required to ensure that veterans receive quality healthcare.

During this period, two facilities had significant deficits in their overall quality improvement processes[1]. Dallas and Altoona had significant deficits in the management and operation of their quality assurance programs. Altoona has significantly improved the overall quality of its programs as reported in their follow up CAP report[2]. The Dallas VA medical center (VAMC) has recently had a change in senior leadership and we will monitor their progress and reevaluate their quality assurance programs.

VHA facilities maintain a strong patient complaint program and have improved these programs between fiscal year (FY) 2003 and FY 2005 with improved data analysis and resulting actions. VHA's patient safety handbook requires that adverse events be

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[1] *Combined Assessment Program Review of the James E. VanZandt VA Medical Center Altoona, PA*, Report No. 03-03208-76, February 2, 2004; *Combined Assessment Program Review of the VA North Texas Health Care System, Dallas, Texas*, Report No. 04-01878-34, November 26, 2004.
[2] *Combined Assessment Program Review of the James E. Van Zandt VA Medical Center Altoona, Pennsylvania*, Report No. 06-00008-130, April 17, 2006.

disclosed to affected patients. VHA made improvements in this effort with 25 percent of the facilities in FY 2003 having appropriate processes in place as evaluated during the CAP inspections and 86 percent of programs in FY 2005 having appropriate programs in place. OIG inspectors report that this process would be improved with a more consistent definition of situations that should be disclosed, given the variety of methods used to review clinical care (peer review, morbidity and mortality review, patient safety reviews).

The OIG recommended VHA issue a new program directive on utilization management when CAP data suggested that facilities were not meeting goals for admission appropriateness and utilization review programs were having less impact. A new program directive was issued by VHA and became effective on July 1, 2005. We will monitor the implementation of this policy through CAP inspections.

The OIG finds that documentation of the use of restraints is well performed in 88 percent of facilities. The OIG believes that this is an area that can be improved. The use of templates in the electronic medical record has improved documentation that is required with the use of restraints at facilities that utilize medical record templates. VHA's quality management processes, which in most facilities are excellent, have shown continued improvements over the last 4 fiscal years. Analysis of mortality data is routinely appropriately performed at VHA facilities in an attempt to trend outcomes.

The OIG believes that there is room for improvement in the re-privileging process. In FY 2005, 84 percent of the facilities analyzed the minimum required data for re-privileging providers, which is a decrease from 90 percent of facilities in FY 2004 and 94 percent in FY 2003. In addition to CAP data, the OIG issued three recent reports[3], which suggest that further attention is required to the re-privileging of credentialed

[3] *Review of a Surgical Technician's Duties John D. Dingell VA Medical Center, Detroit, MI*, Report No. 05-02986-125, April 21, 2006; *Healthcare Inspection Operating Room Nurses Scope of Practice Issues Edward Hines, Jr. VA Hospital, Hines, IL*, Report No. 05-01552-102,March 10, 2006; *Healthcare Inspection Credentialing and Privileging Irregularities at the South Texas Veterans Health Care System San Antonio, Texas,* Report No. 06-00703-147, May 22, 2006.

providers and the determination of the scope of practice for non-credentialed providers. These efforts to improve re-privileging should strengthen the importance and value of the peer review process.

Patient Safety and the Operating Room

At Tampa VAMC and Bay Pines VAMC, procedures designed to ensure that instruments and prosthetics were properly sterilized and cleaned broke down. This resulted in either cancelled surgeries with significant disruption to the function of the hospital or patient exposure to improperly sterilized prosthetic devices.

The modern operating room requires the use of complex equipment, reusable medical supplies, and novel prosthetic devices. Additionally there is a requirement to document and then retrieve data regarding procedures should a patient safety issue arise after the procedure has been completed. The OIG issued a report on a review of the use of improperly sterilized skull implants in the repair of skull defects at the Tampa VAMC[4]. The review revealed that there was a break in sterile procedure during the repair of a skull defect in two veterans. To date, the OIG has not identified any adverse patient outcomes as a result of these errors. The medical needs of those veterans who were placed at risk from these breaks in sterile procedure were promptly addressed by the VHA. VHA alerted its own National Center for Patient Safety (NCPS) and the Food and Drug Administration (FDA) of the facts surrounding these cases. The review reached several conclusions:

- Two patients were affected: one patient received a non-sterile implant and another patient was exposed to a non-sterile implant. Neither patient experienced any complications.
- The redundancy built into the system for verification that products taken into the operating room are sterile failed in these two cases.

[4] *Health Care Inspection Quality of Care in Cranial Implant Surgeries at James A. Haley VA Medical Center Tampa, Florida,* Report No. 06-01642-126, April 10, 2006.

- Accurate reporting up the chain of command was impeded by difficulty in retrieving information regarding what custom implants were utilized in which patients.

The review made two recommendations:

- Review and modify policy and procedures on sterilization, and make appropriate changes to ensure products from all sources are sterilized before delivery to the operating room.
- Review and modify policy and procedures that identify non-autologous products that remain with the patient after a surgical procedure.

The Under Secretary for Health agreed with the findings and has implemented a plan to address the issues. In addition, he committed that VHA would (a) monitor facility progress involving surgical equipment inventory management and oversight of vendor negotiations and (b) NCPS would work in coordination with FDA and other agencies to determine whether more universal safety checks should be applied.

In FY 2004, the OIG inspected the Bay Pines VAMC[5] at the request of Congress and the Secretary because the operating room was closed in November of 2003 and February of 2004 because of serious deficiencies in the process that provides sterilized surgical instruments and equipment to the operating room. VAMC managers cancelled 81 surgeries because critical surgical supplies and instruments were not consistently sterilized by the Supply Processing and Distribution section of the hospital. This inspection also found deficiencies in sterilization techniques, inventory practices and staff training. VHA agreed to correct these practices. A follow up evaluation[6] of the Bay Pines VAMC was published on June 12, 2006.

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[5] *Interim Report – Patient Care and Administrative Issues at VA Medical Center Bay Pines, Florida)*, Report No. 04-01371-108, March 19, 2004; *Issues at VA Medical Center Bay Pines, Florida and Procurement and Deployment of the Core Financial and Logistics System (CoreFLS)*, Report No. 04-01371-177, August 11, 2004.

[6] *Healthcare Inspection Follow-Up Evaluation of Clinical and Administrative Issues Bay Pines Health Care System Bay Pines, Florida*, Report No. 06-01217-154, June 12, 2006.

The VA NCPS posted an alert on its website on April 3, 2006, with instructions on how to properly clean and sterilize a reusable transrectal ultrasound transducer assembly that was in use at VHA facilities. Having determined that sterilization and cleaning procedures in use at the VA medical center were not sufficient, VHA employees worked with the NCPS to correct this problem within VHA. VHA is now in the process of notifying those exposed to the improperly cleaned and sterilized transrectal ultrasound transducer that they may be at risk of serious illness.

It is time for VHA to review all aspects of the processes required to ensure that physicians performing procedures are provided with the proper equipment in the proper state of sterilization and cleanliness. The task is now probably too complex to expect that the technicians in every VHA facility should have to identify from non standard instruction sets the sterilization routine for each of the many items that are used in procedures at a hospital every day. The processes involved in assuring that properly cleaned and sterilized instruments, supplies, and prosthetics are delivered to the operating room needs review and modification to lessen the chance that patients are placed at risk.

Other Quality of Care Issues

Patient safety is improved when management provides the required oversight to ensure that otherwise routine activities are properly conducted. As a result of a March 16, 2004, incident in which the San Juan VA[7] Medical Center ran out of oxygen as the result of breakdowns in routine procedures, the OIG reviewed selected aspects of oxygen management during the CAP process. The OIG made recommendations at 15 of 23 sites reviewed by the CAP process in FY 2005[8] to emphasize the importance of following routine and appropriate procedures to ensure each hospital had adequate supplies of this necessary commodity.

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[7] *Audit of Medical Oxygen Supply Management Practices VA Medical Center San Juan, Puerto Rico,* Report No. 04-01901-19, November 3, 2005.

[8] *Summary report of Combined Assessment Program Reviews at Veterans Health Administration Medical Facilities October 2004 through September 2005*, Report No. 06-01754-123, March 31, 2006.

Patient safety, quality of medical care, and economy often improved when VHA has in place effective policies that standardize medical care. The prevention and management of pressure ulcers is one area in which quality medical care is likely to decrease the average length of stay at VA facilities. The OIG reported on VHA pressure ulcer management[9] and encouraged VHA to develop and implement a policy to address the management these patients. Aspiration pneumonia is a common problem in the hospital setting that has significant quality of care and financial implications. The OIG issued a report on VHA practices regarding the management of patients with feeding and swallowing disorders[10] who are at risk for aspiration pneumonia. VHA agreed with our findings and is making improvements in the management of patients with this condition. The OIG has in a similar fashion reviewed sedation practices outside the operating room at VA medical facilities, reported our findings[11], and made recommendations for improvements which VHA agreed to implement.

Recent natural and man made disasters have demonstrated the importance of a healthcare system to be prepared for the unexpected. The OIG reviewed, through the CAP process, aspects of medical facilities disaster plans[12] and made recommendations to medical facilities and national leadership to improve compliance with guidance provided in the *Veterans Affairs Emergency Preparedness Act of 2002* (P.L. 107-287). We found that VHA facilities were in general in compliance with the law and we made recommendations to address areas where improvement was needed to include education for employees on emergency procedures and high-risk laboratory safety conditions.

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[9] *Healthcare Inspection Management of Patients with Pressure Ulcers in Veterans Health Administration Facilities*, Report No. 05-00295-109, March 22, 2006.
[10] *Healthcare Inspection Evaluation of the Management of Patients with Feeding and Swallowing Problems in Veterans Health Administration Facilities*, Report No. 03-00494-110, March 22, 2006.
[11] *Healthcare Inspection Evaluation of Management of Moderate Sedation in Veterans Health Administration Facilities,* Report No. 04-00330-15, November 1, 2005.
[12] *Emergency Preparedness in Veterans Health Administration Facilities,* Report No. 04-03266-51, January 16, 2006.

VHA has used performance metrics to drive change in clinical areas. As part of a review of VHA clinical outcomes, the OIG evaluated and reported[13] on the VHA performance metric that was designed to improve VHA colon cancer management. This metric, created in 2000, was met if 72 percent of veterans over 51 years of age were screened using standard screening procedures for colon cancer. In our review of patients who were diagnosed with colon cancer, we found that 92 percent of those in the sample were either screened or did not require screening. This is significantly better than the VHA performance metric standard and much better than measures of non-VA populations, where data is available. However, we found that patients who were screened and had a result that indicated that they were at increased risk for colon cancer, were not rapidly provided with the diagnostic evaluations required to make a diagnosis of cancer. Once the diagnosis was made, we found that care was expeditiously provided. As a result of our review, VHA has agreed to review colon cancer management practices and to issue new guidance on the management of this condition by September 30, 2006.

The OIG values and understands the many important contributions that are made to the medical care of veterans by the faculty and trainees at the Nation's medical schools. Important also is the positive interaction that veterans have with young physicians who gain insight into the history of our country from veterans that they have only otherwise read about in books. VHA has policies in place to ensure that veterans receive appropriate medical care independent of the level of training of the members of the treatment team. The OIG will continue to work with VHA to monitor these policies and to ensure that veterans receive proper medical care and trainees receive proper training. The OIG has reported on a number of isolated cases[14] that deal with aspects of this issue and will continue to be vigilant in this area to ensure that VHA standards are upheld.

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[13] *Healthcare Inspection Colorectal Cancer Detection and Management in Veterans Health Administration Facilities*, Report No. 05-00784-76, February 2, 2006.

[14] *Healthcare Inspection Resident Supervision Issues in the Operating Room William Jennings Bryan Dorn VA Medical Center, Columbia, SC*, Report No. 05-03084-135, May 9, 2006; *Resident Supervision in the Operating Room, Birmingham VA Medical Center, Birmingham AL*, Report No. 05-02925-100, March 10, 2006; *Alleged Failure to Supervise Hand Surgery Fellows VA Boston Healthcare System, Boston MA*, Report No. 05-02023-73, February 1, 2006.

Summary

The OIG is committed to working with VHA to insure that veterans receive appropriate, high-quality, healthcare.

Mr. Chairman, thank your again for this opportunity and I would be happy to answer any questions that you or other members of the Subcommittee may have.

United States Government Accountability Office

GAO

Testimony

Before the Subcommittee on Oversight and Investigations, Committee on Veterans' Affairs, House of Representatives

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VA HEALTH CARE

Patient Safety Could be Enhanced by Improvements in Employment Screening and Physician Privileging Practices

Statement of Laurie E. Ekstrand
Director, Health Care

GAO-06-760T

June 15, 2006

GAO
Accountability·Integrity·Reliability

Highlights

Highlights of GAO-06-760T, a testimony before the Subcommittee on Oversight and Investigations, Committee on Veterans' Affairs, House of Representatives

VA HEALTH CARE

Patient Safety Could be Enhanced by Improvements in Employment Screening and Physician Privileging Practices

Why GAO Did This Study

In its March 2004 report, *VA Health Care: Improved Screening of Practitioners Would Reduce Risk to Veterans*, GAO-04-566, GAO made recommendations to improve VA's employment screening of practitioners. GAO was asked to testify today on steps VA has taken to improve its employment screening requirements and VA's physician credentialing and privileging processes because of their importance to patient safety. This testimony is based on two GAO reports released today that determined the extent to which (1) VA has taken steps to improve employment screening for practitioners by implementing GAO's 2004 recommendations, (2) VA facilities are in compliance with selected credentialing and privileging requirements for physicians, and (3) VA has internal controls to help ensure the accuracy of privileging information.

What GAO Recommends

In its reports released today, GAO recommends that VA expand its employment screening oversight program to include all practitioners, provide guidance on collecting physician performance information, enforce the time frame to submit information on paid VA malpractice claims involving VA practitioners, and instruct facilities to establish internal controls for physician privileging information. VA agreed with the findings and conclusions and concurred with the recommendations in both reports.

www.gao.gov/cgi-bin/getrpt?GAO-06-760T.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Laurie E. Ekstrand at (202) 512-7101 or ekstrandl@gao.gov.

What GAO Found

In its report released today, *VA Health Care: Steps Taken to Improve Practitioner Screening, but Facility Compliance with Screening Requirements Is Poor*, GAO-06-544, GAO found that VA has taken steps to improve employment screening for practitioners, such as physicians, nurses, and pharmacists, by partially implementing each of four recommendations GAO made in March 2004. However, gaps still remain in VA's requirements. For example, for the recommendation that VA check all state licenses and national certificates held by all practitioners, such as nurses and pharmacists, VA implemented the recommendation for practitioners it intends to hire, but has not expanded this screening requirement to include those currently employed by VA. In addition, VA's implementation of another recommendation—to conduct oversight to help facilities comply with employment screening requirements—did not include all screening requirements, as recommended by GAO.

In another report released today, *VA Health Care: Selected Credentialing Requirements at Seven Medical Facilities Met, but an Aspect of Privileging Process Needs Improvement*, GAO-06-648, GAO found at seven VA facilities it visited compliance with almost all selected credentialing and privileging requirements for physicians. Credentialing is verifying that a physician's credentials are valid. Privileging is determining which health care services—clinical privileges—a physician is allowed to provide. Clinical privileges must be renewed at least every 2 years. One privileging requirement—to use information on a physician's performance in making privileging decisions—was problematic because officials used performance information when renewing clinical privileges, but collected all or most of this information through their facility's quality assurance program. This is prohibited under VA policy. Further, three of the seven facilities did not submit medical malpractice claim information to VA's Office of Medical-Legal Affairs within 60 days after being notified that a claim was paid, as required by VA. This office uses such information to determine whether VA practitioners have delivered substandard care and provides these determinations to facility officials. When VA medical facilities do not submit all relevant information in a timely manner, facility officials make privileging decisions without the advantage of such determinations.

VA has not required its facilities to establish internal controls to help ensure that physician privileging information managed by medical staff specialists—employees who are responsible for obtaining and verifying information used in credentialing and privileging—is accurate. One facility GAO visited did not identify 106 physicians whose privileging processes had not been completed by facility officials for at least 2 years because of inaccurate information provided by the facility's medical staff specialist. As a result, these physicians were practicing at the facility without current clinical privileges.

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss efforts by the Department of Veterans Affairs (VA) to ensure that its health care practitioners provide safe care to veterans. Specifically, I want to discuss findings related to patient safety in two reports that we are releasing today. The first report focuses on employment screening requirements that VA medical facility officials must follow. Under these requirements, VA facility officials check the professional credentials and personal backgrounds for all practitioners their facilities employ.[1] VA practitioners include physicians, nurses, and pharmacists, among others. Part of the screening process includes credentialing, which is the process of checking that a practitioner's professional credentials, such as licensure, education, and training, are valid and meet VA's requirements for employment. Our second report specifically examines credentialing and privileging processes intended to ensure the safe delivery of care by VA physicians.[2] Physician privileging is the process for determining which health care services or clinical privileges, such as surgical procedures or administering anesthesia, a physician can provide to VA patients without supervision. These clinical privileges must be renewed at least every 2 years. While VA's requirements cannot guarantee patient safety in health care settings, they are intended to minimize the chance of patients receiving care from someone who is incompetent or who may intentionally harm them.

In March 2004, we reported and testified before this subcommittee on gaps in VA's practitioner screening requirements.[3] We found that VA did not require that all of its health care practitioners with access to patients be thoroughly screened. In addition, we found mixed compliance with VA screening requirements at the medical facilities we visited. We concluded that the gaps in and mixed compliance with VA's screening requirements created vulnerabilities that could allow VA to employ health care

[1]GAO, *VA Health Care: Steps Taken to Improve Practitioner Screening, but Facility Compliance with Screening Requirements Is Poor*, GAO-06-544 (Washington: D.C.: May 25, 2006).

[2]GAO, *VA Health Care: Selected Credentialing Requirements at Seven Medical Facilities Met, but an Aspect of Privileging Process Needs Improvement*, GAO-06-648 (Washington, D.C.: May 25, 2006).

[3]GAO, *VA Health Care: Improved Screening of Practitioners Would Reduce Risk to Veterans*, GAO-04-566 (Washington, D.C.: Mar. 31, 2004), and *VA Health Care: Veterans at Risk from Inconsistent Screening of Practitioners*, GAO-04-625T (Washington, D.C.: Mar. 31, 2004).

practitioners who could place patients at risk. In our 2004 report, we made four recommendations to address the gaps we identified in VA's screening requirements and the noncompliance we found at the VA medical facilities we visited. VA generally agreed with our findings and conclusions and stated it would develop a detailed action plan to implement our recommendations.

The subcommittee is interested in the progress VA has made in implementing our March 2004 recommendations and in efforts by VA to ensure that its health care practitioners are qualified and have appropriate backgrounds to safely deliver care to veterans. My remarks today focus on the extent to which (1) VA has taken steps to improve employment screening for practitioners by implementing the four recommendations made in our March 2004 report, (2) VA medical facilities are in compliance with VA's employment screening requirements for health care practitioners, (3) VA medical facilities are in compliance with selected credentialing and privileging requirements for physicians, and (4) VA has internal controls to help ensure the accuracy of information medical facilities use to renew physicians' clinical privileges.

In carrying out this work, we reviewed VA's policies and procedures for employment screening and interviewed VA headquarters officials to determine if the recommendations we made in March 2004 were implemented. We also reviewed VA policies outlining the processes for credentialing and privileging physicians. In addition, we visited seven VA medical facilities for each report.[4] At each facility we visited, we reviewed a sample of practitioner files to determine if documentation in the files demonstrated compliance with the requirements in our reviews. For the employment screening report, we selected five employment screening requirements, and for the physician credentialing and privileging report, we selected four credentialing and five privileging requirements for physicians. See appendix I for the four recommendations we made in March 2004 and the VA screening, credentialing, and privileging requirements we used in our reports to measure VA medical facility compliance. We also identified the internal controls VA has in place for its privileging process and, using GAO's standards for internal controls in the

[4]For the employment screening report, we visited VA facilities in Fargo, North Dakota; Kansas City, Missouri; Miami, Florida; New Orleans, Louisiana; Salt Lake City, Utah; San Antonio, Texas; and Washington, D.C. For the physician credentialing and privileging report, we visited VA facilities in Boise, Idaho; Kansas City, Missouri; Las Vegas, Nevada; Lexington, Kentucky; Martinsburg, West Virginia; Miami, Florida; and San Antonio, Texas.

federal government, determined whether these controls are adequate.[5] We performed our work from April 2005 to May 2006 in accordance with generally accepted government auditing standards.

In summary, VA has taken steps to improve employment screening of its health care practitioners by partially implementing each of the four recommendations made in our March 2004 report; however, gaps still remain in VA's health care practitioner screening requirements. For example, for our recommendation that VA check all state licenses and national certificates held by all practitioners, VA implemented the recommendation for practitioners it intends to hire, but has not expanded this screening requirement to include those currently employed by VA. In addition, VA's implementation of another recommendation—to conduct oversight to help facilities comply with employment screening requirements—did not include all types of practitioners and screening requirements, as we recommended.

At the seven VA medical facilities we visited for our review of VA's health care practitioner screening, we found poor compliance with four of the five VA screening requirements we selected for review. Based on the practitioner files we reviewed, we found that none of the facilities we visited had a compliance rate of 90 percent or more for all screening requirements, and VA policy requires 100 percent compliance with these requirements.[6]

At the seven VA medical facilities we visited for our review of VA's physician credentialing and privileging requirements, we found compliance with almost all selected credentialing and privileging requirements. Specifically, the physician files we reviewed demonstrated compliance with the four selected credentialing requirements and four of the five privileging requirements. Compliance with a fifth privileging requirement—to use information on a physician's performance in making privileging decisions—was problematic at six of the VA medical facilities. At these six, officials obtained this information from their facilities' quality

[5]GAO, *Internal Control Management and Evaluation Tool*, GAO-01-1008G (Washington, D.C.: August 2001).

[6]A 90 percent compliance rate means that 90 percent of the health care practitioner files we examined at each facility provided documentation that the screening requirement had been met in accordance with VA policy.

assurance programs.[7] Use of such information in connection with privileging is prohibited by VA policy, and according to VA officials, this prohibition exists to protect the confidentiality of quality assurance information and to encourage physicians to participate in quality assurance programs. VA has not provided guidance to help medical facilities find alternative ways to efficiently collect performance information, outside of a facility's quality assurance program, that could be used in the renewal of clinical privileges. At the seventh medical facility, officials did not use performance information to renew physicians' clinical privileges, as required. Further, three of the seven facilities did not submit medical malpractice claim information to VA's Office of Medical-Legal Affairs within 60 days after being notified that a claim was paid, as required by VA. This office is responsible for forming panels of practitioners to determine whether VA practitioners have delivered substandard care. When VA medical facilities do not submit all relevant information in a timely manner, facility officials make privileging decisions without the advantage of such determinations.

VA has not required its medical facilities to establish internal controls to help ensure that physician privileging information managed by medical staff specialists—employees who are responsible for obtaining and verifying the information used in credentialing and privileging—is accurate. One facility we visited did not identify 106 physicians whose privileging processes had not been completed by facility officials for at least 2 years because of inaccurate information provided by the facility's medical staff specialist. As a result, these physicians were practicing at the facility without current clinical privileges. This facility has since implemented internal controls to reduce the risk of a similar situation occurring in the future. During our visits to other VA facilities for the physicians' credentialing and privileging report, we did not identify any facilities that had established internal controls to help ensure the accuracy of physician privileging information.

[7]VA requires each of its medical facilities to have a quality assurance program. In general, the VA quality assurance program consists of specified systematic health care reviews carried out by or for VA for the purpose of improving the quality of medical care or the utilization of health care resources in VA facilities. See 38 C.F.R. § 17.500 (2005). These programs collect data on various clinical process and outcome measures involving physicians and other types of practitioners. The measures may include a surgeon's complication rate or a physician's prescribing of medications. Medical facility officials use these measures to look for undesirable patterns and trends in performance.

To better ensure the safety of veterans receiving health care at VA facilities, in our reports we recommended that VA expand its oversight to include a review of VA facilities' compliance with screening requirements for all types of health care practitioners, provide guidance to medical facilities on how to collect individual physician performance information in accordance with VA's credentialing and privileging policy to use in the renewal of physicians' clinical privileges, and enforce the requirement that medical facilities submit information on paid VA medical malpractice claims in a timely manner to VA's Office of Medical-Legal Affairs. Additionally, we recommended that VA instruct its medical facilities to establish internal controls to ensure the accuracy of their physician privileging information. In commenting on drafts of these reports, VA agreed with our findings and conclusions and concurred with our recommendations. VA provided an action plan to address the three recommendations in the report on VA's physician credentialing and privileging requirements, and stated that it will provide an action plan to implement the recommendations in the practitioner screening report after issuance of the report.

Background

VA operates the largest integrated health care system in the United States, providing care to nearly 5 million veterans per year. The VA health care system consists of hospitals, ambulatory clinics, nursing homes, residential rehabilitation treatment programs, and readjustment counseling centers. In addition to providing medical care, VA is the largest educator of health care professionals, training more than 28,000 medical residents annually, as well as other types of trainees.

State Licenses and National Certificates

VA requires its health care practitioners to have professional credentials in their specific professions through either state licenses or national certificates.[8] VA policy requires officials at its medical facilities to screen each applicant for positions at VA to determine whether the applicant possesses at least one current and unrestricted state license or an appropriate national certificate, whichever is applicable for the position sought by the applicant. VA also requires officials at its medical facilities to periodically verify licenses or national certificates held by health care

[8]Not all VA practitioners, such as nursing assistants, are required to have a state license or a national certificate. Some practitioners, such as occupational therapists, may hold both national certificates and state licenses.

practitioners already employed at VA. In general, for both applicants and employed health care practitioners, VA's employment screening process proceeds in two stages. First, applicants and employed health care practitioners are required to disclose to VA, if applicable, their state licenses and national certificates. Applicants disclose their credentials to VA during the application process, and employed health care practitioners disclose credentials to VA as they expire and are renewed with the state licensing board or certifying organization. Second, VA facility officials are required to check whether the disclosed credentials are valid.

State licenses are issued by state licensing boards, whereas national certificates are issued by national certifying organizations, which are separate and independent from state licensing boards. Both state licensing boards and national certifying organizations establish requirements that practitioners must meet to be licensed or certified. Licensed practitioners may be licensed in more than one state. "Current and unrestricted licenses" are licenses that are valid and in good standing in the state where issued. To keep a license current, practitioners must renew their licenses before they expire. When licensing boards discover a licensee is in violation of licensing requirements or established law, for example, abusing prescription drugs or intentionally or negligently providing poor quality care that results in adverse health effects, they may place restrictions on or revoke a license. Restrictions from a state licensing board can limit or prohibit a practitioner from practicing in that particular state. Some, but not all, state licenses are marked to indicate whether the licenses have had restrictions placed on them. Practitioners, such as respiratory and occupational therapists, who are required to have national certificates to work at VA, must have current and unrestricted certificates. National certifying organizations can restrict or revoke certificates for violations of the organizations' professional standards. Generally, each state licensing board and national certifying organization maintains a database of information on restrictions, which employers can often obtain at no cost either by accessing the information on a board's Web site or by contacting the board directly.

Background Investigations

In addition to holding valid professional credentials, when hired, health care practitioners are required to undergo background investigations that verify their personal and professional histories.[9] Depending on the position, the extent of the background investigations for health care practitioners varies. For example, the minimum background investigation is a fingerprint-only investigation, which compares a practitioner's fingerprints to those stored in criminal history databases. A traditional background investigation, which covers a health care practitioner's personal and professional background for up to 10 years, is the most common type of background investigation conducted by VA on its health care practitioners. The traditional background investigation verifies an individual's history of employment, education, and residence, and includes a fingerprint check against a criminal-history database. The Office of Personnel Management conducts background investigations for VA. To determine the level of background investigation required for employment, VA facility officials are required to complete VA Form 2280, which documents the level of risk posed by a particular position.

Physician Credentialing and Privileging

For physicians, VA has specific requirements that facility officials must follow to credential and privilege physicians. Officials must follow these requirements when physicians initially apply to work in VA—which is known as initial appointment—and then again at least every 2 years when physicians must apply for reappointment in order to renew their clinical privileges. Prior to working at VA, physicians enter into VetPro, a Web-based credentialing system VA implemented in March 2001, information used by VA medical facility officials in the credentialing process. For example, physicians enter information on their involvement in VA and non-VA medical malpractice claims and their medical education and training. For their reappointments, physicians must update this credentialing information in VetPro. A facility's medical staff specialist then performs a data check to be sure that all required information has been entered into VetPro. In general, the medical staff specialist at each VA medical facility manages the accuracy of VetPro's credentialing data. The medical staff specialist verifies, with the original source of the information, the accuracy of the credentialing information entered by the physicians. Once a physician's credentialing information has been verified,

[9]Executive Order 10450, April 27, 1953, requires all persons employed by federal departments and agencies to undergo background investigations to ensure that their employment is consistent with national security interests.

the medical staff specialist sends the information to the physician's supervisor, known as a clinical service chief.[10]

In addition to entering credentialing information into VetPro, physicians complete written requests for clinical privileges. The facility medical staff specialist provides a physician's clinical service chief with the requested clinical privileges and information needed to complete the privileging process, including information that indicates that the credentialing information entered by the physician into VetPro has been verified with the appropriate sources. The requested clinical privileges are reviewed by the clinical service chief, who recommends whether a physician should be appointed or reappointed to the facility's medical staff and which clinical privileges should be granted. For reappointment only, VA's policy requires that information on a physician's performance, such as a physician's surgical complication rate, be used when deciding whether to renew a physician's clinical privileges. Based on the physician's performance information, the clinical service chief recommends that clinical privileges previously granted by the facility remain the same, be reduced, or be revoked, and whether newly requested privileges should be added.[11] The 2-year period for renewal of clinical privileges and reappointment to the medical staff begins on the date that the privileges are approved by the medical facility's director.

VA Has Taken Steps to Improve Employment Screening Requirements, but Gaps Remain

VA has taken steps to improve employment screening of its health care practitioners by partially implementing each of the four recommendations made in our March 2004 report; however, gaps still remain in VA's health care practitioner screening requirements. To address our recommendation that VA facility officials contact state licensing boards and national certifying organizations to verify all licenses and certificates held by all VA health care practitioners, VA expanded its verification requirement to include licenses and certificates for all prospective hires but did not extend this requirement to include all practitioners currently employed by VA. For those currently employed, such as nurses and pharmacists, VA only required facility officials to physically inspect one license of a

[10]Clinical services may include surgery, medicine, and radiology.

[11]Reduction of privileges may include restricting or prohibiting a physician from performing certain procedures or prescribing certain medications. Revocation of privileges refers to the permanent loss of all clinical privileges at that facility.

practitioner's choosing.[12] Physical inspection of a license cannot ensure that it is valid and without restriction, nor can it ensure that there are not other licenses from other states that may have restrictions. Checking all licenses against state records is the only way to identify practitioners with restricted licenses. We reviewed a draft of a VA policy that if issued in its current form would fully address our recommendation to require medical facility officials to verify all state licenses and national certificates of currently employed health care practitioners. According to a VA official, this policy is expected to be issued in June 2006.

To address our second recommendation that VA query the Department of Health and Human Services' (HHS) Healthcare Integrity and Protection Data Bank (HIPDB) for all licensed health care practitioners that VA intends to hire and periodically query it for those already employed, VA in July 2004 directed facility officials to query HIPDB for all applicants for VA employment. However, officials were not directed to periodically query HIPDB for health care practitioners currently employed by VA. Officials told us that VA is working with HHS to develop a process whereby VA can electronically query HIPDB for current VA employees. Once this process is in place, and VA is using it to periodically query HIPDB for those currently employed at VA, the department will have fully implemented our recommendation. However, VA did not provide a time frame for implementing this electronic query of HIPDB.

To address our third recommendation that VA expand the use of fingerprint-only background investigations for all practitioners with direct access to patients, VA issued a policy that required all VA medical facilities to begin using electronic fingerprint machines by September 1, 2005. By February 1, 2006, all but two facilities had obtained the equipment necessary to implement this requirement.

To address our fourth recommendation concerning oversight of the screening requirements, VA formalized an oversight program within its Office of Human Resource Management to include a review of some aspects of the screening process for applicants and current employees. However, the oversight program does not ensure that facilities are complying with all of VA's key screening requirements, as we recommended. For example, officials from the oversight program are not required to check personnel files to ensure that facility officials query

[12] *VA Handbook 5005*, pt. II, ch. 3, para. 17a(1).

HIPDB and verify all health care practitioners' licenses and certifications with the relevant issuing organizations.

VA Facilities Did Not Comply with Employment Screening Requirements for Practitioners

For the seven VA facilities we visited to determine compliance with employment screening requirements for practitioners, we found poor compliance with four of the five requirements we selected for review. Two of these five requirements VA implemented since our March 2004 report—for individuals VA intends to hire, query HIPDB and use an employment checklist to document the completion of employment screening requirements. Three other employment screening requirements were long-standing—verify health care practitioners' state licenses and national certificates; complete VA Form 2280, which is used to determine the appropriate type of background investigation needed for each health care practitioner job category; and conduct background investigations. In order to show the variability in the level of compliance among the facilities, we measured their performance against a compliance rate of at least 90 percent for each of the screening requirements, even though VA policy requires 100 percent compliance with these requirements. None of the facilities had a compliance rate of 90 percent or more for all screening requirements we reviewed. Table 1 summarizes the rate of compliance among the seven facilities.

Table 1: Facilities' Rates of Compliance with Select VA Screening Requirements, 2005

	Facility compliance with screening requirements[a]						
Screening requirements	Facility A	Facility B	Facility C	Facility D	Facility E	Facility F	Facility G
Conducting background investigations	○	○	○	○	●	○	○
Position risk level determined (VA Form 2280)	○	○	○	●	●	○	○
Querying HIPDB[b]	○	○	○	●	●	○	○
Completing employment checklist[c]	○	○	○	○	○	○	○
Verifying license, certification, or both	●	●	●	●	○	●	○

○ Indicates a compliance rate of less than 90 percent

● Indicates a compliance rate of 90 percent or greater

Source: GAO analysis of VA facility files.

Notes: We considered facilities to be in compliance if they were able to provide documentation not available in the personnel file. Site visits to these seven VA facilities were conducted from April 2005 through August 2005. Only salaried practitioners are represented in this table.

[a]Tested for significance at the 95 percent confidence level.

[b]Applies only to health care practitioners hired on or after October 1, 2004, and certain health care practitioners hired prior to this date, such as physicians and dentists. Results for this screening requirement cannot be generalized to the facility being reviewed because of the sample size.

[c]Applies only to health care practitioners hired on or after October 1, 2004. Results for this screening requirement cannot be generalized to the facility being reviewed because of the sample size.

As shown in table 1, while two facilities performed HIPDB queries on individuals they intended to hire, one of these facilities completed the queries immediately prior to our visit and not at the time the individuals were hired. We also found that two facilities had created their own employment checklists, but had not included all of the screening requirements contained in the original checklist issued by VA. As a result, these facilities were not in compliance with VA's requirement.

Physician Files at Facilities Demonstrated Compliance with Almost All Selected Credentialing and Privileging Requirements; Not All Facilities Submitted Paid Malpractice Claim Information in a Timely Manner

We found that the physician files at the facilities we visited demonstrated compliance with four VA credentialing and four privileging requirements we reviewed.[13] However, we found that there were problems complying with a fifth privileging requirement—to use information on a physician's performance in making privileging decisions. In addition, we found that three of the seven medical facilities we visited did not submit to VA's Office of Medical-Legal Affairs information on paid VA medical malpractice claims within 60 days after being notified that a claim was paid, as required by VA policy.

Selected Physician Files at Facilities Demonstrated Compliance with Four VA Credentialing and Four Privileging Requirements; a Fifth Privileging Requirement Was Problematic

We found that the physician files at the facilities we visited demonstrated compliance with four VA credentialing and four privileging requirements we reviewed. For the physician files we reviewed, the VA facilities' medical staff specialists contacted state licensing boards to ascertain the status of the state medical licenses held and disclosed by their physicians.[14] They also queried the Federation of State Medical Boards (FSMB) database, as required, to obtain additional information on the status of physicians' medical licenses, including those that may not have been disclosed by physicians.[15] Medical staff specialists complied with the requirement to contact sources, such as courts of jurisdiction, to verify information on physicians' involvement in medical malpractice claims, including ongoing claims, disclosed by physicians. Additionally, in all cases medical staff specialists queried the National Practitioner Data Bank

[13]Findings for the credentialing and privileging requirements cannot be generalized to the facility being reviewed because of the sample size.

[14]VA medical facility officials may also verify physicians' licenses by querying a state licensing board's Web site for information on the licenses.

[15]VA requires facility officials to query FSMB at initial appointment only. Thereafter, VA headquarters regularly receives reports from FSMB on any currently employed VA physician whose name appears on FSMB's list, indicating that disciplinary action has been taken against the physician's state license.

(NPDB) to identify those physicians who have been involved in paid medical malpractice claims, including any physicians who failed to disclose involvement in such claims. The physician files also demonstrated compliance with four of VA's privileging requirements. Medical staff specialists verified physicians' state licenses and the information disclosed by physicians about their involvement in medical malpractice allegations or paid claims, which are both credentialing and privileging requirements. We also found that medical staff specialists verified that physicians had the necessary training and experience to deliver health care and perform the clinical privileges physicians requested. Additionally, after medical staff specialists performed their verification, clinical service chiefs reviewed this information, as required, along with information on physicians' health status.

While we found evidence demonstrating compliance with four of VA's privileging requirements, the files we reviewed showed that there were problems complying with a fifth privileging requirement that is used only in the renewal of privileges—to use information on a physician's performance in making privileging decisions. VA requires that during the renewal of a physician's clinical privileges, VA clinical service chiefs use information on a physician's performance to support, reduce, or revoke the clinical privileges the physician has requested. However, as stated in VA policy, physician performance information that is collected as part of a facility's quality assurance program cannot be used in a facility's privileging process. According to VA, the confidentiality of individual performance information helps ensure practitioner participation, including that of physicians, in a medical facility's quality assurance program by encouraging practitioners to openly discuss opportunities for improvement in practitioner practice without fear of punitive action. VA officials stated that quality assurance information if used outside of a facility's quality assurance program could be available for other purposes, including litigation. However, VA has not provided guidance on how facility officials can obtain such information in accordance with VA policy—that is, outside of a quality assurance program. Officials at six medical facilities told us that they used performance information to support the granting of clinical privileges requested by their physicians, but collected all or most of this information through facility quality assurance programs. At the seventh medical facility, officials did not use individual physician performance information to renew physicians' clinical privileges, as required by VA.

Not All Facilities Submitted Paid Malpractice Claim Information in a Timely Manner

We also included in our review a requirement that is related to the privileging process—medical facilities must submit to VA's Office of Medical-Legal Affairs information on paid VA medical malpractice claims within 60 days after being notified that a claim was paid. VA's Office of Medical-Legal Affairs is responsible for forming panels of practitioners to determine whether practitioners involved in any of these claims delivered substandard care to veterans and provides these determinations to facility officials. We found that three of the seven VA medical facilities we reviewed did not submit claim information to VA's Office of Medical-Legal Affairs within the 60-day time frame. For example, for one facility we visited, we found that from 2001 through 2005, information on 21 of the facility's 26 paid medical malpractice claims had not been submitted within the 60-day time frame to VA's Office of Medical-Legal Affairs.[16] Moreover, on average this medical facility took 30 months to submit information to VA's Office of Medical-Legal Affairs, whereas the other two facilities averaged about 5 months to submit information.

When VA medical facilities do not submit all relevant claim information to the Office of Medical-Legal Affairs, determinations on substandard care are not available to facility officials when they make privileging decisions. In addition, substandard care determinations are required to be reported by facility officials to NPDB. When VA medical facilities do not send claim information in a timely manner to the Office of Medical-Legal Affairs, these cases, if substandard care is found, go unreported or reporting to NPDB is delayed. This prevents other VA and non-VA facilities where the physician may also practice from having complete information on the physician's malpractice history.

[16]As of March 31, 2006, this medical facility had sent all delinquent medical malpractice claim information to VA's Office of Medical-Legal Affairs.

VA Has Not Established Internal Controls to Help Ensure the Accuracy of Facilities' Privileging Information

VA has not required its medical facilities to establish internal controls to help ensure that privileging information managed by medical staff specialists is accurate. One facility we visited did not identify 106 physicians whose privileging processes had not been completed by facility officials for at least 2 years because of inaccurate information provided by the facility's medical staff specialist. According to facility officials, the medical staff specialist changed reappointment dates for some physicians and for other physicians removed their names from VetPro, the facility's credentialing database. As a result, these physicians were practicing at the facility without current clinical privileges.

Once medical facility officials became aware of the problem, they reviewed the files of all physicians and identified 106 physicians for whom the privileging process had not been completed. Facility officials told us they did not find any problems that would have warranted the 106 physicians' removal from the facility's medical staff or that placed veterans at risk. This facility has since implemented internal controls to reduce the risk of a similar situation occurring in the future. During our site visits to other VA medical facilities for the physicians' credentialing and privileging report, we did not identify any facilities that had established internal controls to help ensure the accuracy of the information they use to renew physicians' clinical privileges. Without accurate information, VA medical facility officials will not know if they have failed to renew clinical privileges for any of their physicians.

Concluding Observations

VA's employment screening requirements are intended to ensure the safety of veterans receiving care by identifying practitioners who are incompetent or may intentionally harm veterans. In our practitioner screening report that we are releasing today, we continue to raise concerns about gaps in VA's employment screening requirements. Although VA concurred with our March 2004 recommendations and took steps to implement them, none were fully implemented as of March 2006. These recommendations should be fully implemented. We are also concerned that compliance with employment screening requirements for practitioners, including physicians, nurses, and pharmacists, among others, continues to be poor at the facilities we visited. Continuing gaps in VA's employment screening requirements and mixed compliance with these requirements continue to place veterans at risk.

The other report that we are releasing today demonstrates that medical facilities we reviewed largely complied with VA's physician credentialing and privileging requirements. However, we identified problems with the

appropriate use of physician performance information in the privileging process and the timely submission of medical malpractice information to VA's Office of Medical-Legal Affairs. Additionally, VA's lack of internal controls for its facilities to ensure the accuracy of physician privileging information raises concerns that VA is at risk for allowing physicians to practice with expired clinical privileges.

Our reports include the following four recommendations that VA should implement to help ensure patient safety:

- expand the human resource management oversight program to include a review of VA facilities' compliance with employment screening requirements for all types of practitioners,
- provide guidance to medical facilities on how to collect individual physician performance information in accordance with VA's credentialing and privileging requirements to use in medical facilities' privileging processes,
- enforce the requirement that medical facilities submit information on paid VA medical malpractice claims to VA's Office of Medical-Legal Affairs within 60 days after being notified that the claim is paid, and
- instruct medical facilities to establish internal controls to ensure the accuracy of their physician privileging information.

Mr. Chairman, this concludes my prepared remarks. I will be pleased to answer any questions you or other members of the subcommittee may have.

Contacts and Acknowledgments

For further information regarding this testimony, please contact Laurie E. Ekstrand at (202) 512-7101 or ekstrandl@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this testimony. Mary Ann Curran, Martha Fisher, Krister Friday, and Marcia Mann also contributed to this statement.

Appendix I: March 2004 Report Recommendations and VA Screening, Credentialing, and Privileging Requirements

In our March 2004 report, *VA Health Care: Improved Screening of Practitioners Would Reduce Risk to Veterans*, we made four recommendations to address the gaps we identified in VA's employment screening requirements and the noncompliance we found at the four medical facilities we visited.[1]

March 2004 Report Recommendations

- Expand verification of all state licenses and national certificates by contacting the appropriate licensing boards and national certifying organizations for all Department of Veterans Affairs' (VA) health care practitioners.
- Expand query of the Healthcare Integrity and Protection Data Bank (HIPDB)—a national data bank that contains information on health care practitioners involved in health care-related civil judgments and criminal convictions or who have had disciplinary actions taken against their licenses or national certificates—to include all licensed health care practitioners at VA facilities.
- Conduct fingerprint-only background investigations for all VA health care practitioners with direct patient care access.
- Conduct oversight of medical facilities to ensure compliance with all of VA's key screening requirements.

VA Employment Screening Requirements for Practitioners Selected for Review

To measure facility compliance with VA's employment screening requirements, we selected five requirements for our review.[2] We selected two of the five requirements because in our March 2004 report we found that VA facilities had problems complying with these two long-standing requirements. We selected two other requirements because VA implemented these since March 2004 to improve its employment screening of practitioners. The remaining requirement is long-standing, but is related to the performance of background investigations, which was a requirement we reviewed and found compliance with this requirement to be problematic in 2004.

- Complete VA Form 2280, which medical facility officials must do in order to determine the appropriate type of background investigation needed for each health care practitioner job category.
- Perform a background investigation.

[1]GAO-04-566.

[2]GAO-06-544.

- Query HIPDB.
- Complete an employment checklist, which VA officials are to use to document the completion of VA screening requirements for those practitioners VA intends to hire.
- Verify the status of state licenses and national certificates.

VA Physician Credentialing Requirements Selected for Review

We selected four of VA's credentialing requirements for review because they are requirements that—unlike other credentialing requirements—address information about physicians that can change or be updated with new information periodically.[3]

- Verify that all state medical licenses held by physicians are valid.
- Query the Federation of State Medical Boards database to determine whether physicians had disciplinary action taken against any of their licenses, including expired licenses.
- Verify information provided by physicians on their involvement in medical malpractice claims at VA or non-VA facilities.
- Query the National Practitioner Data Bank to determine whether a physician was reported to this data bank because of involvement in VA or non-VA paid medical malpractice claims, display of professional incompetence, or engagement in professional misconduct.

VA Physician Privileging Requirements Selected for Review

We selected four privileging requirements that VA identifies as general privileging requirements. In addition to the four general privileging requirements, we selected another privileging requirement because of its importance in the renewal of clinical privileges because it provides clinical service chiefs with information on the quality of care delivered by individual physicians.[4]

- Verify that all state medical licenses held by physicians are valid.
- Verify physicians' training and experience.
- Assess physicians' clinical competence and health status.
- Consider any information provided by physicians related to medical malpractice allegations or paid claims, loss of medical staff membership, loss or reduction of clinical privileges at VA or non-VA facilities, or any challenges to physicians' state medical licenses.

[3]GAO-06-648.

[4]GAO-06-648.

- Use information on physicians' performances when making decisions about whether to renew physicians' clinical privileges.

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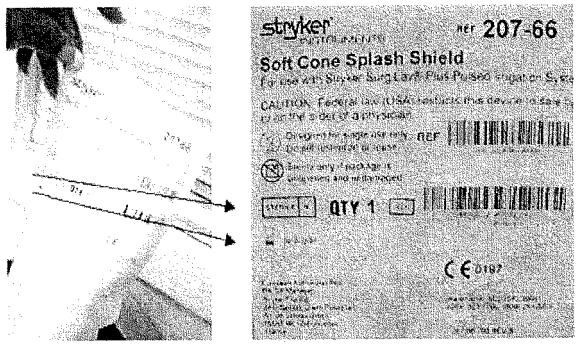
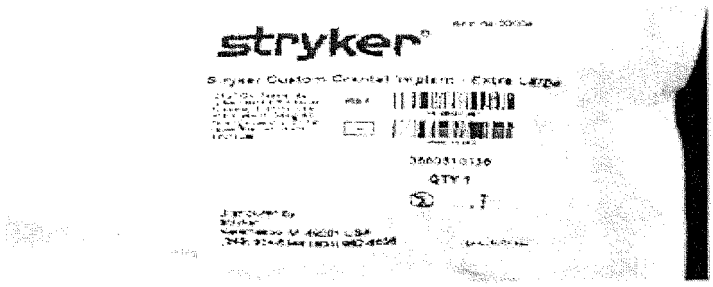


As shown in the pictures above, pre-packaged sterile products have sterilization or expiration dates, an hour glass, and the word "Sterile" printed on the package. On the day following the February 28 procedure, while investigating the placement of a non-sterile model on the sterile field, OR staff became aware that the Stryker® custom cranial implant itself also required sterilization by the facility

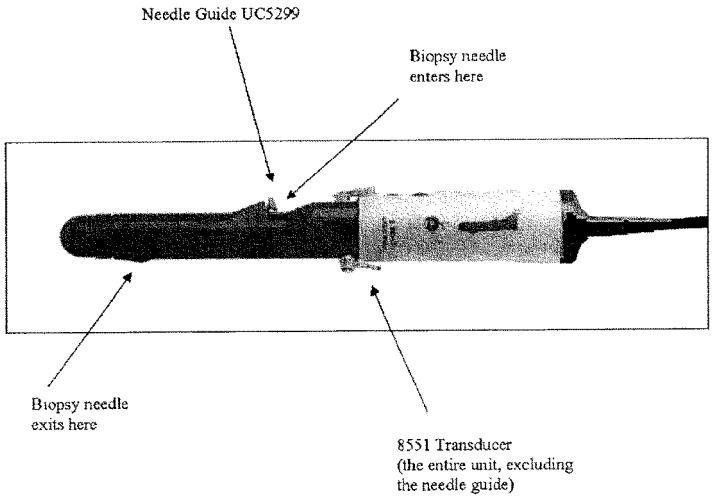
Although the Stryker® implant was in a peel package, in the final analysis, the package did not have the word sterile or an hour glass printed on it (see the following picture). OR nursing staff and scrub techs did not verify sterility indicators, the surgeon did not question the sterility of product, and all JAHVAMC staff present in the OR incorrectly assumed that the implant and model were sterilized by the manufacturer. We concluded that ultimately this policy was not followed during the procedures on February 21 and February 28



Source: *Health Care Inspection Quality of Care in Cranial Implant Surgeries at James A. Haley VA Medical Center Tampa, Florida* Report No. 06-01642-126 April 10, 2006, pages 15-16, Available: http://www.va.gov/oig/54/reports/VAOIG-06-01642-126.pdf

AL06-011
Attachment #2:
B-K Medical Model 8551 Transducer Assembly

Model 8551 Transducer Assembly: Scan with or without biopsy



Source: VA Patient Safety Alert AL:06-011, April 3, 2006, page 4.
Available: http://www.va.gov/ncps/alerts/B-KMedicalTransducerAlert06-011.pdf

James P. Bagian, M.D., PE
U.S. Department of Veterans Affairs

Dr. Bagian, your testimony states "the misguided belief that accountability systems and punishment are the primary and most effective means to achieve improvement in patient safety." Please discuss the role accountability plays in patient safety.

Understanding that reporting problems and potential problems is an important part of the system.

> Please elaborate on the VA reporting systems and how they promote reporting.
>
> How are these reporting systems promulgated to the medical professionals and patient population?

How does VA track the use of medical devices? Can you verify the accuracy of reporting the use of medical devices? How can VA track the use of medical devices and not know how many convicted sex offenders it employs?

Did the VA include FDA in discussions with Stryker and B-K regarding the problems with the respective devices?

Please describe the reporting system or systems used by VA to identify medical errors.

> Which system of reporting was used for the incident at the Togus facility?
>
> Which system was used in Tampa?

Regarding the incident at the Haley VAMC in Tampa, how were other patients that may have received a cranial implant identified? The IG report mentions that there was confusion over how many patients may have received this particular implant, what procedures does VA have in place to monitor devices used on patients? What guidance does FDA provide for monitoring medical devices?

What is the procedure for notifying other VAMCs of a problem that could occur in other facilities?

What is the procedure for notifying FDA on potential problems with medical devices? Please describe communications with FDA on the cranial plate and transducer. What has your past experience been with FDA on issues relating to medical devices?

How does VA follow-up internally on problems that have been identified at a facility? How do they follow-up with FDA on problems that they have brought to the attention to the agency?

What is the process for items to be taken to the operating room? Who is in charge of making sure a device is sterile? What are the procedures?

The IG recommended that VHA facilities take action to reduce delays in performing diagnostic GI procedures to improve screening for colorectal cancer. Are you aware of actions taken by VHA facilities to improve screening, and is there specific guidance provided by the NCPS in conducing colorectal cancer screenings?

As Director of the National Center for Patient Safety, what is your role in managing medical equipment and oversight of its use?

John D. Daigh, Jr., M.D.
Department of Veterans Affairs

Yesterday, at the Full Committee hearing we heard that the VA had not implemented recommendations from the IG and GAO.

> When the IG issues its CAP reports, do VHA and the Medical Centers take steps to enact corrective measures to remedy the problems? Are these recommendations implemented in a timely fashion?

Your testimony states that there is room for improvement on re-privileging. How often does re-privileging occur, and has the IG seen problems with initial privileging?

How can VA assure that their Operating Room procedures are followed to avoid a breakdown in surgical procedures? Is additional training needed for OR staff?

Will the safety checks mentioned in testimony be applied systematically throughout VHA facilities or just in Tampa?

What lessons has the IG seen to improve patient safety in the event of another natural disaster as widespread as Hurricane Katrina was last summer?

In its Summary Report of CAP Reviews at VHA Medical Facilities, October 2004-September 2005, the Office of Inspector General noted that timeliness issues in the screening of colorectal cancer and diagnosis was a problem. The OIG recommendation was to reduce delays in performing diagnostic procedures. What other actions could VHA take to improve colorectal cancer screening?

What can the IG tell the Committee about Information Security as it relates to secure access and patient records? How is information controlled at VA Medical facilities?

Daniel Schultz, M.D.
Food and Drug Administration

Does the FDA monitor VA Patient Safety Alerts?

What does the FDA do with VA Patient Safety Alerts?

Is the FDA involved in preparation of the Patient Safety Alert?

Does the FDA recommend VHA work with them to modify procedures to ensure OR safety and medical device safety?

Please describe the role of FDA in ensuring patient safety through medical devices.

How does FDA follow-up that devices are used properly and identify possible problems?

Please, for our understanding, walk the Subcommittee through a typical notification process of a problem with a medical device?

What actions did the FDA take when notified of the problem with the cleaning of the transrectal ultrasound transducer?

Does the FDA know how many facilities, federal and non-federal that use a transrectal ultrasound transducer? Is the FDA aware of another device that can be used to biopsy for colorectal cancer? What outreach does FDA provide to notify medical facilities about a possible problem with a medical device?

How does the FDA monitor the use of medical devices?

Does the FDA have a policy on reporting medical errors on items that require FDA approval?

What is the FDA policy on monitoring controlled substances?

Laurie Ekstrand
U.S. Government Accountability Office

Yesterday, the Full Committee held a hearing on GAO and IG recommendations that VA failed to implement related to Information Technology. Doe it alarm you that VA has only partially implemented some of the 2004 recommendations related to credentialing and privileging?

Does VA impose the same requirements on credentialing and privileging on contract medical professionals that it requires for in-house practitioners?

Is there a penalty for the two facilities that did not purchase finger print machines? Have they purchased them now? Is there an incentive for them to purchase?

How difficult would it be to adapt VetPro to include privileging information or is there a commercial of the shelf (COTS) product to provide electronic tracking of privileging information?

As a follow-up to a 2004 report, GAO recently conducted another review of credentialing at VA medical facilities. Please describe the steps VA has taken to improve credentialing and privileging at its facilities.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 3 2006

The Honorable Michael Bilirakis
House of Representatives
Washington, D.C. 20515-0909

Dear Mr. Bilirakis:

This is in response to your June 20, 2006, letter in follow-up to the testimony provided by Dr. Daniel Schultz at the June 15, 2006, hearing before the House Committee on Veterans' Affairs, Subcommittee on Oversight and Investigations, on patient safety issues. In that letter, you requested information on the Food and Drug Administration's (FDA or the Agency) authority to require that device labels be clearly marked for sterilization, and, for devices requiring cleaning or sterilization, clear instructions to medical personnel on these procedures. In addition, you asked the Agency to provide information on FDA's authority to require changes in labeling to clearly and conspicuously indicate whether a device is sterile and to provide concise instructions on the cleaning and sterilization of devices.

When submitting 510(k) pre-market notifications, manufacturers are required to provide labeling that is sufficient to describe the device, including the indications for use, device description, and directions for use (Title 21, Code of Federal Regulations [CFR], section 807.87[e]). In addition, all devices are subject to the general labeling provisions set forth in 21 CFR part 801. FDA reviews the labeling information submitted in a 510(k) along with other data as part of the basis for its decision to clear a device for marketing. Accordingly, FDA has authority to refuse to clear pre-market notifications that do not include adequate labeling information.

FDA has additional authorities to ensure that sterilization procedures and device labeling are well-controlled under the Quality System Regulation (QSR) for medical devices (21 CFR part 820). All manufacturers must conform with design controls (21 CFR 820.30), which include evaluation and control of human factors that may contribute to adverse events when the device is used in its intended setting. Thus, compliance with design controls requires clear, useful labeling. In addition, the QSR requires manufacturers of devices intended for reuse to validate their cleaning procedures. Such validation includes subjecting the device to a "worst case scenario." For example, in the case of a transrectal transducer, test soils are used to mimic protein residuals that can remain after routine use. Devices that are not manufactured in accordance with QSR are considered adulterated under section 501 of the Federal Food, Drug, and Cosmetic (FD&C) Act and could be subject to enforcement action. In addition, section 502 establishes standards for misbranding under the FD&C Act. Among other things, a device may be misbranded if its labeling is false or misleading or if it fails to bear adequate directions for use. A device requiring disinfecting or sterilization before use that did not have adequate labeling to describe these procedures could be found to be misbranded. Misbranded

devices are subject to enforcement action, such as seizure, injunction, and civil money penalties.

FDA has issued a number of guidance documents that address the issues raised at the hearing. FDA has in place a 1996 guidance entitled "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities, FDA Reviewer Guidance." The document notes that the recommendations contained in it also are applicable to devices provided non-sterile and intended to be sterilized by the end user. In these cases, the guidance recommends that staff review the sterilization instructions provided in the labeling for clarity. Another guidance that is applicable to labeling for products that are intended to be sterilized prior to use is "Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA."

Agency staff is currently in the process of reviewing and revising these guidance documents. The recent incidents at the VA hospital have highlighted changes in hospital and industry practices over the years that require us to update our guidance and review procedures for certain products. While many user facilities receive and use sterile implantable devices, other hospitals prefer to receive these devices non-sterile so they can examine, manipulate, and size prior to implantation. In that practice scenario, hospitals are required to sterilize the device themselves prior to implantation in accordance with manufacturer instructions. In recognition of these differing practices, we intend to revise our guidances to advise manufacturers of the need to clearly label devices as "NON-STERILE" if there is the possibility that the device could be shipped both sterile or non-sterile. We expect to begin issuing these updates before the end of the fiscal year.

FDA also issued guidance in 1997 entitled "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." The guidance informs manufacturers that labeling for transducers supplied non-sterile or intended for reuse should include one of two things: (1) recommended procedures to clean and disinfect the transducer between uses, with validation of the procedures provided in the pre-market submission; or (2) a recommendation for a cleared liquid sterilant or disinfectant product with appropriate instructions in the labeling. The guidance also discusses the recommendations for the labeling and the need to provide instructions for care of the device between uses including storage, cleaning, disinfection, and sterilization of all components.

The Agency takes very seriously the two incidents discussed at the June 15, 2006, hearing and intends to use its authority and resources to avoid future incidents. For example, FDA has worked with Stryker Leibinger to improve the labeling on its custom Cranial Implant. As a result, Stryker has revised its labeling to prominently state "Non-Sterile" on the outer box (two locations), Instructions for Use, and inner product pouch. In addition, the Agency's Public Health Notification: *FDA Public Health Notification: Reprocessing of Reusable Ultrasound Transducer Assemblies Used for Biopsy Procedures* issued on June 19, 2006. You can find it on our webpage at: *www.fda.gov/cdrh/safety/061906-ultrasoundtransducers.html*. This notification, which went out to over 45,000 subscribers on our list server, including healthcare providers and hospitals, reminds users of the importance of properly cleaning and disinfecting invasive ultrasound devices between patient use, and stresses the need to follow individual manufacturer's instructions for reprocessing the

transducer assemblies because each brand and model of device may require different cleaning and sterilization procedures. The notification was based on FDA's review of information about not only the products involved in the VA hospital incidents, but also on information concerning a variety of ultrasound systems and transducers. The recommendations in this notification apply to users of all devices of these types.

We also note that sterilization information is one of the areas that FDA focused on during its recent quality review initiative. As part of this program, the Agency is enhancing training for both its staff and industry about the types of information that should be submitted and reviewed in medical device pre-market submissions.

We remain committed in our efforts to continue our collaborative work with the Veterans Administration on these important issues. Please let us know if we can provide any additional information.

Sincerely,

Michelle Mittal

for David W. Boyer
Assistant Commissioner
for Legislation