

Deadly sutures in a hospital near you?

Geoff Metcalf interviews class-action attorney Wendy York

Attorney Wendy York may become known as the next Erin Brockovich. York is spearheading a legal effort against Ethicon, Inc., the nation's leading suture manufacturer, which distributed at least 3.6 million packages of contaminated sutures to the public through medical supply distributors, hospitals and physicians several years ago.

Although a recall was issued, many of the contaminated sutures had been used in surgeries and some caused severe postoperative infections. According to the FDA, only 25 percent of the recalled sutures were recovered -- and some may still be on hospital shelves today. Geoff Metcalf recently interviewed York about her efforts on behalf of those who feel they were victimized by Ethicon and its dirty sutures.

By Geoff Metcalf

Question: Please explain for our readers what Ethicon is and how you got involved in this battle?

Answer: Ethicon is a subsidiary company of Johnson & Johnson. They make 80 percent of all medical sutures used in our operations. So, imagine yourself going through a surgery recognizing that 80 percent of all sutures are manufactured by Ethicon. When you go through surgery, every single suture in that surgery *must* be sterile. If they are not sterile, it can cause all kinds of problems such as postoperative infections.

In 1994, Ethicon had a new sterilizer they used to manufacture and sterilize these sutures. They had a problem, and they didn't tell anybody about it. The FDA, which regulates these companies, received an anonymous phone call stating that there was a problem at the Ethicon plant with these vicryl sutures, that there was a problem with contaminated sutures being sent out to the medical community.

Q: What did the FDA do?

A: The FDA did a surprise inspection. They went out to the San Angelo facility, spending almost a week there. They found all kinds of problems and deviations from the manufacturing practices. The FDA sent Ethicon a warning letter in August of 1994 and said: Look, you have a problem. You didn't do anything about it. You deviated from good manufacturing practices and, if you don't address the issue immediately, we will prevent you from getting *any* additional FDA market approvals for any of your other products, as well as prevent you from selling to the U.S. government or contracting with the government.

Q: Wait a minute. So this outfit was manufacturing these surgical sutures, and they *knew* they weren't sterilized?

A: Right.

Q: And they allowed them to be distributed? That's criminal, isn't it?

A: Yes, it's criminal. Well, no, I can't say it's criminal.

Q: Gosh, I thought I just did. If you are distributing something that you know is not sterile

specifically for a sterile environment, I don't see how any PR department can put a benign face on that. Why weren't they sued earlier?

A: Because nobody knew about it. And the way they handled the recall -- it was done in such a quiet, secretive way that even the doctors who were doing the surgery and using these sutures day in and day out did not know that they were contaminated.

Q: When the FDA kicked their butt and told them had to do something to correct the problem, who did they tell that they were recalling these sutures?

A: The FDA did a "warning letter," but what Ethicon did was actually send sales reps out to the hospitals to collect the sutures from the shelves.

Q: Whoa! A medical manufacturer doesn't sell to the hospitals. They sell to a distributor. And a distributor might package them under a different label like "Ralph's Surgical Supplies." So how are they even going to know?

A: Exactly. That was a big problem. For example, Baxter Health Care. They take the sutures and repackage them in their own surgery kits, so on the hospital shelves, you would not see just vicryl sutures; you'd see "Baxter's Surgery Kit." So these sales reps are only looking for the vicryl sutures in the Ethicon packaging and not Baxter's Surgery kits or any other distributors' surgery kits. The way they did this recall was wholly inadequate, but more importantly, the distributors who buy the sutures and then resell them to the hospitals, doctors offices and clinics -- not all of them received the recall notices. So these hospitals continued to receive contaminated sutures unknowingly, and those sutures were being used in patients across the country and internationally.

Q: And they were compelled, in fact they were *ordered* by the FDA to notify these people, and they didn't.

A: Right.

Q: Why isn't the FDA stringing these folks up by their thumbs and eviscerating them in the town square?

A: That's an excellent question. There actually was a congressional inquiry. Two U.S. congressmen, Stark and Waxman, did a congressional inquiry with the FDA -- what is the problem? Why aren't you policing these corporations?

Q: And what did the FDA say when they were called on the congressional carpet?

A: The FDA said: We did the best job that we could with the information. We don't have all the manpower, all the staff to do investigations of every corporation to make sure that they are complying with the regulations for good manufacturing practices. So really, it is a lack of governmental agencies policing the corporations that manufacture our medical supplies and products.

Q: Does anyone have any kind of chain of custody in the inventory control of how many unsterile sutures were distributed? Ethicon must know.

A: Ethicon claims there were 3.6 million. But we have reason to believe that it was potentially over 10 million and that all the sutures manufactured and sterilized during this time period should have been affected by the recall and weren't.

Q: How big a time window are we looking at here?

A: We're talking about sutures that were manufactured and sterilized as early as May of 1994, and it is potentially possible that these sutures can still be on the shelves *today*. However, that possibility gets more and more remote as time goes on.

Q: There are unsterile surgical sutures out there, and they are going to be used. They will be introduced into patients who will probably, eventually get sick, I would suspect, with screaming infections of some kind. What has been the incidence of that? And what, if anything, can these victims do?

A: There is no way to totally know what the incidences are for these postoperative infections, because the doctors were not informed of the recall, so they have no way of knowing that it was the sutures. They just know they have a patient suffering a raging postoperative infection that has resulted in disfigurement, possibly death for an older person or an immune-compromised person or just serious complications requiring multiple surgeries postoperatively. So to answer your question as to the instances -- we don't know, because the recall was done in such a way we will never know.

Q: What kinds of infections have been reported?

A: They are so raging. I spoke to a gentleman who four days after heart surgery had an abscess the size of a basketball on his chest where the surgery was, so they actually had to drain it surgically following his surgery. They weren't dealing with his cardio issues anymore; they were dealing with his infection.

Q: This happened in 1994. Do the people even know in the medical community that if you encounter one of these raging postoperative infections, it could very well be a result of the non-sterile sutures?

A: Possibly, and the only way to find out for these patients across the country is to get their operative reports. If their operative reports say "vicryl sutures" and they had raging infections where their doctors were absolutely puzzled as to what happened ...

Q: We keep saying "raging infection." How bad are they?

A: These infections are not something where you just have a little wound infection where you have pus. These are serious infections. One of the bugs is actually a cousin of tuberculosis. These infections can last anywhere from six months on -- indefinitely -- until you get a specialist to treat the infection.

Q: So this isn't one of those deals where you can pop some penicillin and you're all better?

A: No. I have heard some horrific horror stories of disfigurement, where the infection gets into their blood and into their bones and they have to have their sternum removed because the infection has gone so deep.

Q: How wide was the distribution of these sutures? Can it be isolated to the continental United States? Is it the United States and Europe? Does anybody know?

A: Unfortunately, it was both nationally and internationally. We have received calls from England from patients who suffered infections.

Q: You said something in passing that just clicked a little light off in my head. I recently got

an e-mail from a listener whose son is in the Marines, and suddenly a whole bunch of guys started to test positive for TB. They tested positive for TB, but they say it is not TB. These are military types, and lot of them have been in the Gulf. You mentioned to me earlier that some of these sutures actually made it into the military inventory.

A: Absolutely. A large portion of these sutures were sold to VA hospitals and to the military. So, if you were serving in the Gulf War and you were wounded, most likely vicryl sutures, these Ethicon sutures, were used. So here you are in a foreign country with maybe not the same sterile environment we have in our U.S. hospitals. You add contaminated sutures, and you've got our own military, serving for our country, suffering raging infections because this company has been irresponsible.

Q: How much culpability does Johnson & Johnson have as the parent? Or is this one of those deals where if Ethicon is proven fatally flawed, the parent company just pulls the plug and flushes the sins of the subsidiary? Is there any culpability on the part of the parent company?

A: Absolutely. Johnson & Johnson had so much control of this company of theirs. In fact, Johnson & Johnson was part of the validation process of this new sterilizer that failed. They were also involved in the recall. Johnson & Johnson was also involved in the microbiology testing. So their hands are dirty. Just plain and simple, Johnson & Johnson's hands are dirty.

Q: Process-wise, what stage are you at in litigation?

A: We filed a class action in Texas. It's in East District, Beaumont, Texas. We have a class certification hearing the end of June. We are in the middle of the throes of discovery. And, of course, Ethicon and Johnson & Johnson are playing hardball with discovery. They don't produce documents. If you watched the television series about Wal-Mart and how they play games in discovery, Ethicon makes them look almost saintly.

Q: How does someone find out -- if they are going into surgery, if they've been in surgery, if they are scheduled for surgery -- if they are a potential victim of these dirty sutures floating around out there?

A: If you are scheduled for surgery in the near future, the likelihood that these sutures are on the shelves becomes more and more remote over time. However, you would want to have your physicians or surgeons ensure that the vicryl sutures they will use during the surgery -- and there is a high likelihood they would -- are not part of the list of recalled sutures. We actually have a website that has a list of recalled sutures where physicians, surgeons and hospitals can go to see whether they have any in their inventory.

Q: Let's have the website. We want people to be able to find this for their own personal research.

A: It's [EDITOR'S NOTE: THE WEBSITE NO LONGER EXISTS]-----, or people can call us toll-free at 888-788-8734.

Q: And what does that website have on it?

A: On the left-hand side, there are bulletins that show which recalls are in effect. If you hit that bullet that says "Recall," you will call up several listings of code numbers for the vicryl sutures that were recalled. You can print that out and then you have a list of all the recalled sutures by Ethicon and Johnson & Johnson.

Q: You're telling me someone is scheduled for surgery has to go to the hospital and ask for

item number XC4729759992 dated such and such?

A: There is no expiration date on these sutures, so there is a potential they could be on the shelf. It is unlikely. If you've already had surgery and suffered a major infection, to find out if you are potentially a victim of this corporate irresponsibility, you're going to want to get your operative reports and your medical records to ensure if, in fact, you had vicryl sutures used during your surgery and your infection matches the type that is related to this suture.

Q: In the meantime, I would suspect that if someone has been affected by these tainted sutures, they would be invited to join in this class action? How do they get in touch with whoever the dirty-suture sheriff is?

A: We are the sheriff, because the FDA sure isn't doing it. They can visit our website and e-mail us, or they can call us. All of our phone numbers are on the website.

Q: What *has* the FDA done since you got involved in this?

A: Johnson & Johnson, as you can imagine, is a great PR company. They sent their PR folks down to shmooze FDA and told them, "Look, we're going to correct the problem. This is what we're going to do. We're going to shut the sterilizer down. We're going to do a recall. And we'll follow up on the recall and give you a report as to how many returned products we have received." After going through this whole process of doing the recall and giving reports to the FDA, the FDA was satisfied, but has continued to police Ethicon to make sure they are in compliance with manufacturing practices.

Q: Wendy, if or when someone is having difficulty getting their hands on their operative records or medial records, what can they do?

A: If they need assistance getting their medical records, contact us. They are entitled to them by law. They want to ensure that vicryl sutures were used. If vicryl sutures were used and they had a raging postoperative infection, the next issue becomes, through our expertise, linking these sutures to their infection. Once that's done, the rest is history. They can, if they choose to, become a member of this class action that we have pursued in Texas.

Q: This is outrageous. This is like selling dirty milk to mothers. I don't understand why Johnson & Johnson doesn't step up to the plate and throw themselves on their sword and say, "Mea culpa! Here's a check." Why are they digging in their heels on this?

A: That is an excellent question. For example, with the Tylenol case back in the late '80s, they took responsibility and they tried to handle the situation immediately. In this case, it is Ethicon who is the main culprit, which is their company. I think because Ethicon is implicated and a lot of people don't link Ethicon to Johnson & Johnson, it's not as big of a PR issue for Johnson & Johnson.

Q: They think they've got plausible deniability?

A: Exactly.

Q: But they don't have legal deniability?

A: Oh, no. They recalled their own product. They admitted their product was contaminated. They just recalled it too late, and their recall was completely ineffective.

Q: You said earlier that it was atypical of the FDA to come down as hard as they did when

they came in and ordered Ethicon, in harsh terms, what they had to do.

A: Right.

Q: Why didn't they follow up? Why didn't they come back and say, "Hey, wait a minute. What are you doing just notifying the hospitals? That's bullfeathers! You know to whom you sold this stuff. Let's look at your records." Why did the FDA do such a poor job?

A: It's the government! Do you expect more?

Q: No. We deserve more, but are conditioned not to expect more. I expect less, frankly.

A: It's the *federal* government, which makes it worse. There is nobody policing them. The FDA is so busy doing pre-market approvals for new pharmaceutical drugs or medical products that they are not actually policing these manufacturers when something goes wrong.

Q: I guess the conventional wisdom would be Johnson & Johnson is a big dog.

A: They are.

Q: You might be 90 pounds dripping wet. You are in Sacramento, and these guys can and will paper blizzard you to death.

A: That's true.

Q: They can just wear you down and beat you up and you're going to eventually get tired of this. How do you overcome that?

A: Sheer will power and knowing I'm doing what's right. Besides, I've got great co-counsels and one of the best firms in the country -- in fact, several great firms. One of the leading co-counsel firms is Provost Dunfrey, who has headed the tobacco litigation in Texas. So we have some excellent firms, and we are all teaming together to fight this big Johnson & Johnson company.

Q: At what point do they recognize the diminishing return and cost of delaying what may be inevitable? That movie "Erin Brockovich" -- its success has to add to the cause you're involved with. So when does Johnson & Johnson say, "We just want to settle this matter and make it go away"?

A: When their feet are to the fire, which is going to be just before trial. I suspect that is what it is going to take. Or once we get through discovery and we take some key depositions and they know their feet are to the fire, it's over with. That's what it is going to take.

Q: This seems like such a no-brainer, but I know that so much of this has to do with the process. It doesn't have anything to do with who is right or wrong. They can stall and procrastinate and make it costly for you. This discovery process is really kind of like a game, isn't it?

A: It *is* a game. They are playing a game, and they are playing hardball with their discovery. But, in a sense, it is a business risk they are making too. It's all business.

Q: I recall back during the Ford Pinto flap, they reached a point where they basically did a cost-benefit analysis, asking, "At what point is it cheaper for us to pay the lawsuits than to fix the product?" But that doesn't seem to be the case with Johnson & Johnson. The Ethicon

problem was in a specific window of time from December of '93 to September of '94 with an expendable product.

A: Right.

Q: So it seems their losses are finite.

A: Their losses are finite. They completely shut down that sterilizer and have not used it until they revamped it. So you are right. Their losses are finite. It's a matter of finding out how many people were affected by the product and to what extent were they injured by the product.

Q: Have you had any success in getting a handle on that?

A: Yeah. It is a big task, but we have had significant success, and we get calls every day from potential victims of these sutures.

Q: How did you stumble onto this nightmare?

A: There was one victim who came forward, and the physician told her, "Look, you have been subjected to these contaminated sutures, and there has been a recall." So, she contacted our office and we started representing her. If you go back to the Erin Brockovich example, we started trying to find as many documents as we could through the FDA and doing discovery. One of the local Bay-area newspapers did a story on the case, and when the story came out, we received a ton of phone calls. Two other victims called who had surgery the same day as our first client at that same clinic who also suffered major disfiguring postoperative infections. And the story kept getting bigger and bigger, mushrooming over time to this point.

Q: How many victims are involved in the class action, or is it even public knowledge yet?

A: It's not public knowledge at this point, and it probably won't be until after class certification and class notice goes out to the entire country.

Q: How long does a hospital hang on to sutures once they are presumably sterilized? They are in a bag, right? If the bag isn't open, they could last indefinitely.

A: Right. There was no expiration on these sutures at the time they were manufactured. So, these sutures technically can still be on the shelf, assuming that neither the hospital nor distributor has gone through that supply. There is no expiration date because these sutures are packaged in such a way that they can last for a significant period of time.

Q: I don't understand why there isn't some board somewhere with oversight over Ethicon. What they did was beyond disingenuous. It was bad and done knowingly. That is sleazy. Isn't there any agency tasked with slapping companies like this?

A: No. The FDA is the only agency, and we saw what they did. They sent them a warning letter and then basically let Ethicon handle the recall the way they saw fit. That's it!

Q: So the only recourse available to victims is through the courts?

A: Right. We're really the last civil cop to keep these corporations accountable.

Q: I would expect that the medical community would hop on this too. Obviously, if a guy does what is basically a cosmetic surgery on someone and the patient comes back with some raging infection, she's going to come after the doctor for malpractice. And he and his

insurance company are going to want to say: "Hey, we should be held harmless in this. It was the folks who sold us these dirty sutures." Are you getting any cooperation from doctors?

A: Yes. In fact, there was this doctor who *was* getting sued for malpractice for a postoperative infection. Nobody knew about the recall of the contaminated sutures. The doctor found out about the recall from "20/20" on ABC four years later. So his attorneys are calling us to try to get the information about the contaminated sutures so that they can defend this malpractice action. Doctors who were doing these surgeries did not even know about these contaminated sutures.

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