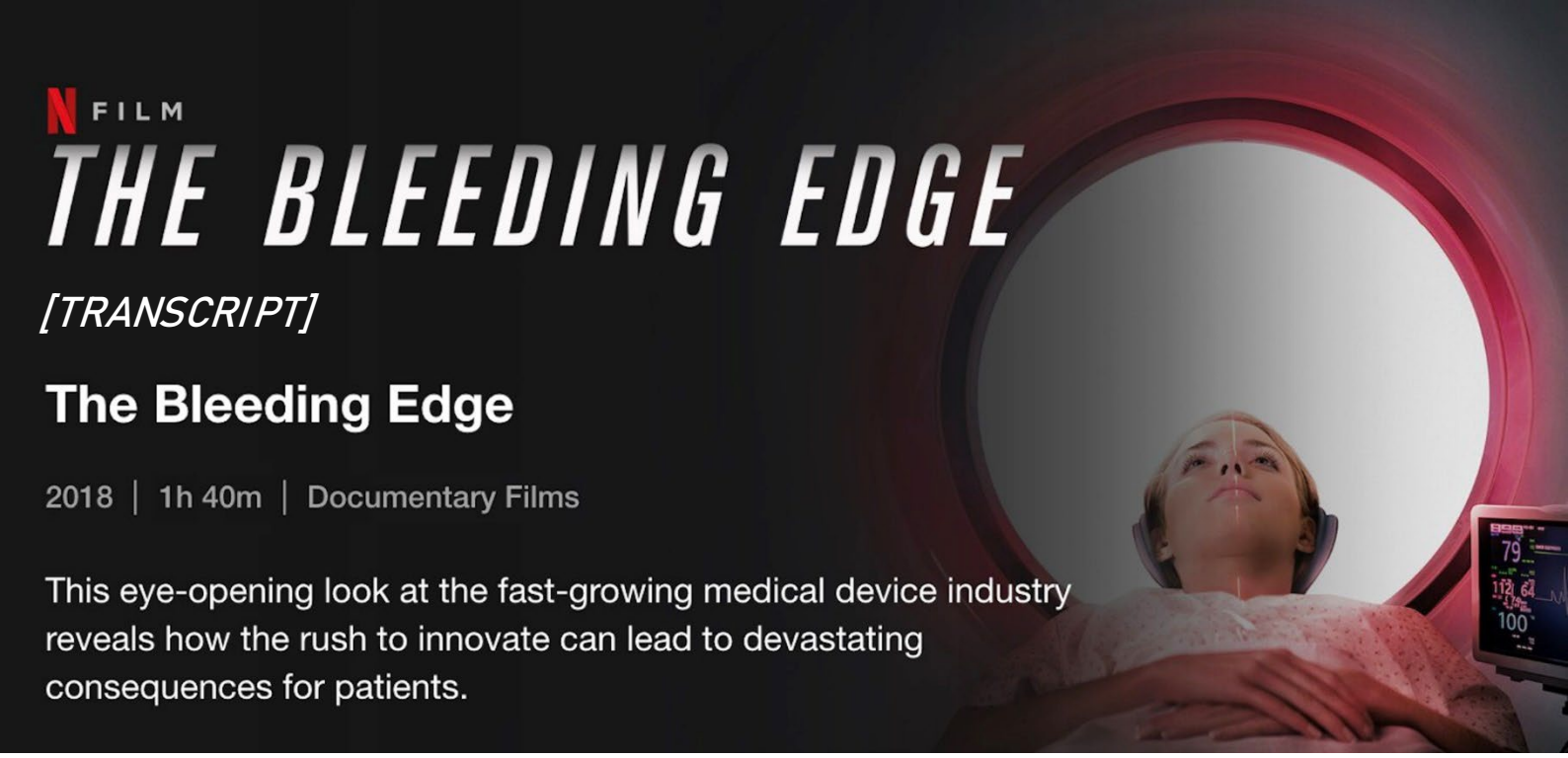

Scott Whitaker, CEO, Advanced Medical Technology Association (addressing the Global Summit for Medical Technology):

Good afternoon, everyone, and welcome to the Global Summit for Medical Technology. Here in this room, many of you have inspired generational leaps in medical technologies. You've created whole new fields of medical advances. You've explored new horizons and broken barriers. And everything we do is a means to the end of unleashing innovation to improve and save lives.

Watches and cell phones that monitor blood sugar.

3-D printers to create prosthetic limbs.

Artificial intelligence that today diagnoses melanoma.

All of these things exist today.

So, let's pause for a minute and take a look at the future.

What if, by 2050, we have micro laboratories implanted in our bodies that predict illnesses before we ever get sick?

What if, by 2050, we have 3-D printers creating custom biomechanical organs?

Or what if artificial intelligence can be used to predict heart attacks before they even happen?

If we succeed... imagine the impact we will have on medical care. Let's continue to improve lives by unleashing innovation.

Jim Spencer, Journalist, Minneapolis Star Tribune:

Before you're born, they use medical devices to find out when you're gonna be born. When you're born, they use medical devices to find out how healthy you are. When you're growing up, they oftentimes use medical devices to enhance what's going on with you. Medical devices are a way of life in America. They are a way of life in post-industrial society. They are a reason, in some ways, for post-industrial society. They help us live longer. They give us better quality of life. And they're just about everywhere.

Jeanne Lenzer, author of The Danger Within Us:

There are devices that are truly lifesaving. My husband has a pacemaker in. I'm glad for it. It saved his life. I have a cataract lens in that makes me see beautifully. It's everything from the very simple little thing like a tongue depressor to breast implants, drug-eluting stents. There's such an array of devices. It's pretty amazing.

Dr Michael Carome, Director, Public Citizen Health Research Group:

The medical device industry is a 300 billion-a-year industry. This is big business.

Jim Spencer, Journalist, Minneapolis Star Tribune:

It's kind of a parallel to the drug industry, and it isn't nearly as well understood.

People think pharma's got power. No, no, no, no. The device industry has much more power than pharma.

Jeanne Lenzer, author of The Danger Within Us:

The medical device industry has been expanding faster than just about any other industry. And that's because technology is just running away right now. And it's running away faster than we're keeping up with the actual science.

Jim Spencer, Journalist, Minneapolis Star Tribune:

We're living in a very highly technological society, and medical technology is a... a wonder and a miracle. But because it's everywhere, we have to be careful.

Over the past ten years, nearly 70 million Americans have been implanted with medical devices.

— Jeanne Lenzer, author of The Danger Within Us

Essure Patients

Angie Firmalino, Essure patient:

I grew up in Western New York, right between Rochester and Buffalo. I'm a mail carrier. And I work in the morning, delivering mail to 70 mailboxes. I'm married. I was engaged to somebody else, and we broke up, and my friends threw me a party to try to make me feel better. And, um, he was driving by, and one of my friends yelled out to him, "Porch party!"

Peter Firmalino:

A friend of mine invited me in, and that's kind of where we met.

What did you like about her?

Peter: Everything.

Angie: My daughter didn't have a father in her life, and Pete's children lost their mother when she passed away. So, to come together and all of us to just have each other, it was just a blessing.

My last child was born in 2009. I was 37 when we became pregnant. We had decided, you know, we wanted to have one together, but that was enough. So, I went and spoke to my ob-gyn. And he talked to me about a new permanent birth control device called Essure, which could be done right in the office, and I could go back to work the next day.

Essure promotional video:

You protect... ...and prevent... ...and even plan ahead. But what about your birth control? Maybe it's time to consider the proven, permanent birth control of Essure.

Dr Julio Cesar Novoa, OB/GYN:

Essure is a permanent sterilisation device. It is made out of little four-centimetre coils. It's inserted through the uterus and placed inside of the fallopian tubes.

It's intentionally designed to cause an inflammatory response, which generates scar tissue. The scar tissue closes off the fallopian tubes permanently, blocking the sperm and the egg from meeting, therefore preventing pregnancy.

The early studies that were done to get this device approved suggested it's 99% effective in closing the fallopian tube and causing sterilization. It originally was designed by Conceptus and then bought by Bayer. It was marketed as a better choice than the traditional tubal ligation.

Essure promotional video:

The Essure procedure does not require any incisions. And because there are no incisions, the procedure does not leave any scars. And when it comes to recovery after the Essure procedure, women were typically discharged from the medical facility within 45 minutes.

Gaby Avina, Former Essure Spokesperson:

It took no time out of my life. And there was no chance of having to go under anaesthesia.

I was a nurse assisting in the placement of Essure during the clinical trials. So, I watched the procedure. I thought it was simple. It was non-surgical, it was permanent, and it was everything I was looking for.

Seeing how easy it was to put it in, I thought I should do it too. For us, we were now allowed to have a type of intimacy... The company liked my story because I was a nurse, I'd participated on both ends of the product. So I was invited to be a spokesperson. I even went so far as I had my own website called Ask Gaby. Patients would to me, doctors would write to me. I told them all the benefits. I used to tell them that it took longer to get your nails done than it did to get sterilised.

Ana Fuentes, Essure patient:

I have a full-time job in a business firm. I am an account executive. I love my job. I have four daughters. And I enjoy every moment with my kids.

My husband and I had decided that four kids was enough. So, when I went to my doctor, my doctor recommended Essure.

He said that it was easy. You come in the office, you leave and you're good. You go back to your normal life.

Essure training video:

Thread the Essure device through the introducer while you hold the hysteroscope. Slowly and steadily advance the Essure delivery system into the fallopian tube.

Ana Fuentes, Essure patient:

He said I shouldn't feel anything. Just two little devices that I wouldn't even notice. But the moment I stepped out of the doctor's office, I started feeling cramping. Then, in the first week, I started bleeding more than I have ever bled in my whole life during a period. I called the doctor. He's like, "Those two little things doesn't do anything, doesn't do all those changes that you're telling me. "So I just kept continuing to believe that it was in my head.

Angie Firmalino, Essure patient:

I went in for the procedure. I could feel the whole thing. I felt it go into my tube. I remember hearing the clicking noises. I felt it expand. Um, it was pretty intense.

After the procedure, I was running fevers a lot. The bleeding was almost continual. There may be a day or two during the month when I wasn't bleeding. The sharp, stabbing pain on my left side was getting more and more intense. So I made an appointment to go in and have an exam.

The doctor ordered an ultrasound. He came in and he looked at the screen and just said, "Oh, it looks like one of her Essure devices is in her uterus."

And I was kind of in shock. So he says, "You know, we need to get these out." And I agreed.

Woke up and the doctor said, "Everything went good." You know. "Go home and heal and rest and you should feel better."

But after the procedure, I started having problems again. The bleeding started picking up. My husband had gone with me to the hospital and we're in a room, and I've got the IV in... and just blood exploded out of me. Like, it looked like a horror scene. And there were large clots all over the floor. And he went out in the hallway and just screamed for someone to come, and they all just came in.

They threw me on a gurney, and off I went, stretcher down the hallway. I was scared. I was really thinking about... "What's gonna happen to my kids if I don't wake up?"

Old black and white FDA public service announcement on medical quackery, phoney devices and machines:

The old-time medicine man would sell his snake oil by positively guaranteeing it would cure any and every disease known to man and beast. Fortunately, this form of quackery in medicine is gradually being eliminated by our food and drug laws, but there's still another form, equally dangerous and far more difficult to control. Phony machines and devices, which are supposed to diagnose and treat disease. Unlike new drugs, therapeutic devices do not have to be proved either safe or effective before they are sold or used.

William K. Hunnard, Former FDA Associate Commissioner:

The history of medical devices is odd. There was an explosion in the 1920s and '30s and '40s of fraudulent devices that pretended to put sound waves into the body to cure cancer or any number of these weird devices. Some were dangerous, such as ones that had radioactive qualities.

Old black and white film on medical quackery, phoney devices and machines:

There are some as phony as a three dollar bill. Like this Zerret Applicator, for example, which has claimed to cure arthritis with Z-rays. There are no Z-rays. Investigate before you invest in health services or products. Help stamp out quackery. This has been a public service announcement from the Food and Drug Administration.

Jeanne Lenzer, author of The Danger Within Us:

For many years, devices just came onto the market with the anecdotes of doctors who used them, who would say, "Well, I think it works." It was only with the Medical Device Amendments of 1976 that devices came under control of FDA.

At that point, industry argued, "We don't want to have to test everything we're already using, pacemakers and other devices." And the FDA said, "Okay, you can grandfather in anything that was on the market prior to 1976.

Dr Michael Carome, Director, Public Citizen Health Research Group:

The regulation of medical devices has always been less than ideal. Since 1976, the complexity of devices, the number of devices, the types of devices, just rapidly expanded. So, we have the same framework that was imposed, you know, 40 years ago for a device world that is much more complicated today.

Dr David Kessler, FDA Commissioner, 1990-1997:

(Addressing House Commerce Subcommittee on FDA Approval Process): Mr. Chairman, Americans rightfully expect public health decisions... to be made in their interest and to be based on the best science and medicine.

I was appointed as FDA commissioner by the first President Bush and asked to stay on by President Clinton. FDA is the most important consumer protection agency in the world. It regulates virtually everything that comes in contact with the body.

FDA is organized by centers. So there's a center for foods. There's a center for drugs, there's a center for biologics and there's a center for medical devices. And FDA does a credible job with the vast majority of products. The problem we have... is that, when it comes to medical devices, we built a system that doesn't work.

Dr Stephen Tower, Orthopedic Surgeon and hip replacement patient:

Before I went into medicine, I worked as a bike mechanic. I always have loved taking things apart and putting them back together again. I grew up in Alaska. Both my parents were physicians, so, I had a lot of knowledge about medicine in general.

Janice Tower, Stephen Tower's wife:

He's probably the most genuine person you'll ever meet. He's very caring, giving, honest, and his patients love him.

Dr Stephen Tower: The first operation I ever saw as a third-year medical student was a hip replacement. And I: loved it. Very mechanical. Something's broken and you fix it. And it's... it's the simplicity of it.

Janice Tower: He was having a lot of degenerative hip issues himself. And, on the one side, the pain was more prevalent and persistent. It was starting to limit his bike riding.

Dr Stephen Tower: The hip was getting progressively more painful. I realized, doing the 100-Mile Winter Race, that I could never do that again unless I got the hip replaced. The most critical fundamental about hip replacement is what are the materials of the parts and pieces that rub together?

The most commonly used combinations are ceramic-on-ceramic, ceramic-on-plastic, metal-on-plastic, and metal-on-metal. The metal is almost exclusively chrome cobalt. Cobalt is used in a lot of machine alloys, because it's made very, very hard. It's one reason that we use it in joint replacement.

I was swayed to the metal-on-metal ASR hip because that particular device had been marketed specifically to exceptionally active individuals. Within six weeks after my operation, I did a 200-mile road race without a lot of difficulty. I... I thought it was great.

Dr Michael Carome, Director, Public Citizen Health Research Group:

Most people probably believe, when they get a medical device implanted, be it a pacemaker or a joint, that those medical devices have undergone appropriate testing to demonstrate that they are safe and effective before they came on the market and doctors started using them. But for most moderate and high-risk devices, that is not the case.

William K. Hunnard, Former FDA Associate Commissioner:

Originally, Congress intended that almost all new devices go through pre-market approval. A PMA is similar to a new drug application, in that a manufacturer must test it first in humans, compile all this data, and then present that to FDA scientists, who will approve the device if in fact it is safe and effective.

Industry argues, "We're innovating, we're changing products every year and that costs a lot of money, to test each of those iterations in humans. So, Congress established the 510(K) process.

Dr Michael Carome, Director, Public Citizen Health Research Group:

For the 510(K) pathway, all the manufacturer needs to demonstrate is that their device is substantially equivalent, is the regulatory term, to another device that's already on the market.

Dr David Kessler, FDA Commissioner, 1990-1997:

That provision, which was meant as an exception, in essence, a little loophole... That exception became the rule. So the vast majority of devices today, regrettably, are regulated under this framework.

Dr Adriane Fugh-Berman, Professor of Pharamcology & Physiology, Georgetown University:

This really can cause problems when one medical device is approved on the basis of being substantially equivalent to a previous medical device that was approved because it was substantially equivalent to an earlier medical device than that.

Dr Deborah Cohen, Associate Editor, BMJ:

You end up with what we call a daisy chain. And then, quite often what you found is that some of these predicate devices, as they call them... have been actually recalled from the market because they've been failing.

Jeanne Lenzer, author of The Danger Within Us:

I called the FDA and asked them, "How can you clear something based on a predicate device that's already been shown to be dangerous? And they said, "We don't judge what the prior device is."

Dr Rita Redberg, Editor, Jama Internal Medicine:

So even if the device was recalled because it was dangerous, you can still use it as a predicate and get your device cleared 'cause it's substantially equivalent. So, there's a lot of problems with that 510(K) system. And that's how metal-on-metal hips got on the market.

Dr Stephen Tower, Orthopedic Surgeon and hip replacement patient:

A year and a half after my operation, I started having a slew of health issues that I hadn't had before. I developed a tremor in my non-dominant hand.

Janice Tower: His ears were ringing. He was starting to repeat himself a lot and explain things... over and over.

Dr Stephen Tower: As time went on, those issues accelerated, and then, I... I had a psychological decompensation.

Janice Tower: He was attending a conference, and I got a call. He had trashed a hotel room. He wrote all over the walls. He took pens, Sharpies, he wrote on the ceiling, he wrote all over. And when that was done, he took soap... and he wrote on the mirrors. It was a full-on breakdown.

You could see it in his eyes. And just... in turmoil... knowing full well... that he'd lost it. All the while, he's still thinking. He's still connecting the dots.

Dr Stephen Tower: Eventually, I started checking my blood and urine. And my levels of cobalt were 100 times what I should have.

I started calling up engineers at DePuy and salespeople, saying, "Is anyone else talking about this?" The answer back was, "No, we've never heard of that being a problem." But it was clear to me that the hip would need to be redone.

So, I chose a different model with a plastic socket and a ceramic head. When my doctor went in there to revise my hip, he found a virtual crankcase of metal sludge. And the critical ligaments, what we call the hip capsule that holds a hip in place, that had just kind of liquefied.

Within a month, I had an incredible recovery in terms of my psychologic symptoms and my ability to think.

Janice Tower: All the other symptoms magically disappeared. I got my husband back.

Dr Stephen Tower: Unless I'd personally experienced this myself... I wouldn't believe an orthopedic implant could cause neurologic problems. But with my experience, I started to notice problems in my own patients, and it's not just metal-on-metal, but metal-on-plastics, too.

Rodney Evans, Dr Tower's hip replacement patient:

I was going blind. I was seeing stars, constant stars in my eyes. Just diagnosed me with Parkinson's. My mind was... slowly slipping away.

Angelia Clark, Dr Tower's hip replacement patient:

I couldn't remember words. I'd start a sentence, then couldn't think of the word that was supposed to go next. I thought I had Alzheimer's or dementia. And that was really scary.

Bill Vigil, Dr Tower's hip replacement patient:

Problems with memory. I was writing it off to, um, aging.

Dr Stephen Tower, Orthopedic Surgeon and hip replacement patient:

I've seen so much of this that now, when a patient comes into the office, if they have an artificial hip and I know it has a chrome cobalt piece, I routinely check the level of cobalt in their urine.

Rodney Evans, Dr Tower's hip replacement patient:

I've just been progressively getting better and better since I had the hips both replaced.

Dr Stephen Tower: It's very hard to convince people this problem exists, unless you show reversibility. Get rid of the cobalt, the problem goes away. It's hard for people to argue with that.

The real breakthrough in the last 18 months has been the ability to actually image the neurologic problem.

Dr Robert Bridges, Diagnostic Radiologist:

Dr. Tower came down to the Imaging Center to look at an MRI of the hip and we got into a discussion about the symptoms of cobalt poisoning toxicity, and he mentioned cognitive issues.

Dr Stephen Tower: Dr. Bridges said, "Gee, yeah, we ought to get an FDG PET brain scan on a patient that you think is having the neurologic problems, because I bet we can see it.

Dr Robert Bridges: We have a tool that can actually detect dementias like Alzheimer's years before they become clinically evident on physical examination.

Basically, what I'm looking at is the slice through the basal ganglia. Blue is bad.

Dr Stephen Tower: Blue is bad. Those are the areas of the brain that are most affected.

Dr Robert Bridges: By this scale, we're looking at 2 to 3 standard deviation. At least greater than two standard deviations below normal.

The first patient came up very abnormal. So then he suggested we do another patient and then another patient, and they all began to look the same.

Dr Stephen Tower: You've got the typical findings on the brain scan that we're seeing with the other 23 patients. So you're number 24.

Dr Stephen Tower: Doing a study on this is something that I feel I'm morally obligated to do. But I don't think I should be the guy who has to do that. This work really needs to be reproduced with hundreds, if not thousands, of patients to fully understand it. I think the CDC should be doing it. I think the FDA should be doing it. And I've approached all those people, and just not getting a lot of support there.

Dr Robert Bridges: I'm horrified because, the more I'm looking at it, I'm beginning to wonder, is cobalt the new mercury poisoning? Are these people being relegated to the dustbin because they have what somebody misperceives as dementia? How many people have been misdiagnosed with a permanent disease process that actually have a reversible disease process? That's the horror right there.

Hip manufacturers recalled some hips containing cobalt because the caused nearby tissue to disintegrate.

The industry continues to recommend hips containing cobalt.

There are now more than ten million people worldwide who currently have hips, knees or shoulders with cobalt.

— Organisation for Economic Co-operation and Development

DePuy Synthes promo:

Innovation lives here. It's the foundation of our legacy and the backbone of our DNA.

Dan Auger, Product Development Director, DePuy Synthes:

Our motto is never stop moving. And some of the words that are behind that are just this relentless pursuit... of innovation that improves patient care.

Dr Deborah Cohen, Associate Editor, BMJ:

Industry likes to use the term innovation, innovation, innovation. Innovation, to me, means we've got something new, but we've got good evidence to support it. We've got good evidence about the benefits and the harms. You're developing medicine, you're bringing it forward. Without evidence, we don't know whether it's really a development. It... You know? Who knows? You don't know.

Dr Stephen Tower, Orthopedic Surgeon and hip replacement patient:

Surgeons and patients like the idea that they're getting something new. I tell my patients new equates to unproven.

Dr Michael Carome, Director, Public Citizen Health Research Group:

Companies can develop new products that may not be safer and more effective than other products already on the market, but they will certainly heavily promote them to doctors, to hospitals, to drive up their profits.

Dr Deborah Cohen, Associate Editor, BMJ:

They wheel out patients and say, "This person wouldn't be alive today if they didn't have this innovative product." It's all very glossy. It's a slick machine.

Kemal Malik, Bayer Board of Management/Innovation:

We've doubled life expectancy in 150 years. And that's happened because of innovation.

Dr Rita Redberg, Editor, Jama Internal Medicine:

Just because you have a new technology doesn't mean it's innovation. And, I think, too often I hear people say, "Oh, you're gonna stifle innovation." They're not talking about stifling innovation. They're talking about stifling, um, putting untested devices on the market. That's not innovative.

Ana Fuentes, Essure patient:

Before Essure, the only times I was in the hospital was because I was pregnant. For the past three years that I had the Essure, I've visited the hospital a lot because of pain. I was working and passed out 'cause of the pain, and I woke up and I drove myself to the hospital. I'm more scared because, if they have to admit me, I have to find someone to take care of my kids. Especially because it's a school night. So I don't want them to miss school.

After Essure, my bleeding wouldn't stop. It came to the point that I had to start wearing baby diapers. I couldn't even function as a wife to my husband, and eventually, he ran away.

One of the doctors that I had, he mentioned that most Latinas have menstrual problems. So they thought it was... because I was Latina that I would bleed a lot. But I'm like, "I've been Latina since I was born, and I became a... And my mom saw me grow up and I never bleeded this much. So, this doesn't have to do with me being Latina."

Angie Firmalino, Essure patient:

I've had a headache since 2011. Normally, the headache's about a four. And then at night, it starts spiking up. Seven, eight, nine. Sometimes ten.

So this is my traction unit. It stretches my cervical spine, 'cause the inflammation gives me insane headaches.

Before I had Essure put in, I was really strong and really healthy. We went hiking, we went camping. I could do all the normal things that moms do. It's hard for me not to be doing those things.

I did a little research. I didn't see too many people online talking about Essure. And I said, "I have to warn my friends and my family members, and I need to tell them to stay away from this." So I started this little Facebook group called Essure Problems, and I added all my girlfriends. I didn't really know much about Facebook groups, but then slowly people that I didn't know started commenting and saying, "Oh, my God, this is what I'm going through."

Just stories just started coming in. People just found me. It just started snowballing. I remember hitting 65 people and going, "Wow, there's 65 people that are having this problem." Every day, we had new people joining the group. Women were telling their stories.

Women's Stories:

"The day that I was implanted, I left the hospital and I was in pain."

"They told me to take some Ibuprofen and it'll get better."

"Now I'm going to the OB this week to have a full hysterectomy at 31 years old."

Angie Firmalino: Slowly, the progression of women joining and having similar stories, um, we became a support group for each other. And then we started finding information about how the device was approved.

We found out that Essure went through something called the pre-market approval process, or PMA.

Dr Diana Zuckerman, President, National Center for Health Research:

Pre-market approval is the most stringent pathway to get a device approved. But even that process is not that strict. It's less rigorous than the process for drugs.

Most drugs had to have two clinical trials, and they have to have large numbers of patients. With devices, it's only one study. Those studies are often small. Sometimes it's 100 people. I've seen studies with 50 people. So the approval process for the riskiest devices is not good.

Angie Firmalino, Essure patient:

One of the members of the group found the transcript for the 2002 approval meeting where the FDA approved Essure. I noticed at the bottom of the transcript that the entire meeting had been videotaped by this video company, and their phone number was there so I thought, "I should call them and see if I can get a copy of that." And so I did, and they found it, and they said it was going to be several hundred dollars. I put a post on the page. I'm like, "I think we need this." And within 15 minutes, we raised $900 on the page, and I ordered those DVDs.

They approved this device on such a small number of women that were followed for such a short amount of time. The lead investigator for the clinical trials who presented the evidence to the FDA on the safety and efficacy of this device, he owned stock in this company.

FDA Premarket approval hearing for Essure, July 22, 2002:

"I have received compensation which now represents a financial interest in the company."

Angie Firmalino: There was a paid spokesperson that had Essure implanted herself. Gabriella Avina. They hired her to come and speak.

Gabriella Avina, Former Essure Spokesperson

It brought about a peace to my life and to my relationship that I cannot express to you.

Angie Firmalino: And it was just mind-blowing because they didn't have a lot of data for the questions the panel members were asking.

FDA Premarket approval hearing for Essure, July 22, 2002:

"What would happen if you touched the electrode to the coils?"

"How much uterine cavity will be compromised?"

"The panel was not supplied with a summary about compatibility testing."

"What about the tubal perforation issue?"

"I don't know what happens to people with metal sensitivity when you implant metals in them."

Angie Firmalino: They still approved it, even with these open-ended questions.

FDA Premarket approval hearing for Essure, July 22, 2002:

The device clearly met the criteria of safety and effectiveness that are required for approval.

Angie Firmalino: At the end of the meeting, one of the panel members asked, "What are we gonna do if we're seeing problems in ten years?"

FDA Premarket approval hearing for Essure, July 22, 2002:

"Private investigators would find each of us, bring us back here, and ask us why we approved this."

[Those present at the hearing all laugh]

Angie: How could they joke about this? Like, they're joking about... us. You know, here we are, ten years later, and all these problems... And... and, you know, they approved it on... on a joke. If this is our FDA process of medical device approval, then we have a big problem in this country, because this is just one device.

Tammy Jackson, surgical mesh patient:

I'm from Nicholasville, Kentucky. Kind of a... Anywhere, USA. It's a small town. Great schools. Great people, wonderful church. I was in nursing. I did paediatrics, uh, children. And I just loved working with the people. My husband is a machinist at General Electric. He works on the machines. They're bigger than a house. He's my rock.

Byron Jackson: Well, we met... Um... I was young and we were out partying. So, um, she was with a group of friends and I was kind of out on my own... um, looking for trouble, I should say. Ah... I found it!

Tammy: We've got a daughter that's got a beautiful spirit. Very loving, very compassionate. Uh, make a great doctor one day, if she chose to. I delivered my daughter at 41 and I was working at the hospital, and when I would go to assist my patients by transporting them from the bed, I would leak some.

Byron: She started having some problem with holding her urine. She went to the doctor to see about it. And, um, of course... they suggested some procedures.

Tammy: My doctor said, "We can take care of that in a simple 45-minute procedure with this new thing called mesh. It's a simple, golden standard outpatient surgery. It's better than sliced bread. It's the new thing."

Adam Slater, Attorney:

Mesh is a polypropylene resin that gets extruded into fibers and then woven and knit into a mesh. Johnson & Johnson first saw that doctors were starting to take hernia mesh and cut very little tiny pieces of it to help support repairs where they felt they needed a little bit extra because the woman's tissue was weak.

So, they said, "That's a great idea. Let's sell the hernia mesh for pelvic floor treatments."

Dr Tom Margolis, OB/GYN:

As women get older, and if they have several children, things start to bulge or drop. Patients come to us and want things to be fixed. One approach is what's called a native tissue repair, which is basically where we suture things in place using stitches, suture material. Or, theoretically, one could use mesh to augment the repair.

The surgeon makes a cut in the vagina and then implants the mesh to hold organs up in place. It costs about $25 to bring to market and they sell for about $2,000 a pop.

Dr Julio Cesar Novoa, OB/GYN:

I was told that it is superior to the traditional surgery that's required. Very easy to place. Very, very few complications.

All vaginal mesh devices were cleared through the 510(K) pathway.

The FDA did not require human studies.

— Heneghan, Goldacre, Onakpoya, et al., 2017

Dr David Kessler, FDA Commissioner, 1990-1997:

I wish I could say that doctors really understood the regulation of medical devices. But the fact is that's not what they do. That's not their area of expertise.

Dr Adriane Fugh-Berman, Professor of Pharamcology & Physiology, Georgetown University:

We were surprised to see how little surgeons knew, in our study, about the approval process for devices. Some of the surgeons seemed to think, "Well, the FDA are taking care of this." That of course these devices had been tested in humans.

Vaginal Mesh Patients

Tammy Jackson, surgical mesh patient:

I came home from my surgery. I started having a lot of pain, discomfort. I couldn't sit, I'd climb steps, I felt like a 90-year-old woman.

Byron Jackson: She had a bad fever. She was throwing up. We ended up going to a few emergency rooms. We'd seen so many doctors. They didn't know what was going on with her. They had no clue.

Dr Tom Margolis, OB/GYN:

Once you put mesh in, it is scarred into place, permanently affixing it to the tissue. The scar tissue causes the mesh to shrink up and as it shrinks, it starts to contract and pull against the adjacent tissues that are in contact with the mesh.

Adam Slater, Attorney:

The scar tissue creates a hard and flexible object in the pelvis. Around the vagina, around the bladder, around the urethra. Structures that need to be able to move in very subtle ways in order to function. Now you have this hard object in there, and there's a cascade of problems.

Vaginal Mesh Patients

Tammy Jackson, surgical mesh patient:

So eventually, I find this doctor in Louisville. And he says, "You've got a problem with your mesh and it needs to be removed... but I can't do it." I was never trained to take it out. I've never took it out. We were just trained on how to put it in.

Dr Tom Margolis, OB/GYN:

Once it's scarred in place... that's it. Ain't coming out. Not in its entirety.

Vaginal Mesh Patients

Tammy Jackson, surgical mesh patient:

I've been told it's like removing rebar out of concrete, bubblegum out of your hair.

Dr Julio Cesar Novoa, OB/GYN:

Because of the position that they're placed, they're in very delicate areas where it's almost impossible to remove the mesh completely Once the scarring is complete, the body doesn't want it to be there. So it keeps scarring and scarring, keeps pushing and pushing, and sometimes it tries to push it out of the body.

Tammy Jackson, surgical mesh patient:

So, we do a partial mesh removal. Six to eight weeks of healing. My husband and I are trying to get back to our sexual relations. I've set the stage, actually. I've got candles going, I've got my daughter in bed. You know, I'm gonna feel like a woman again. This mesh problem's gone.

Very shortly into our intercourse, my husband jumps up.

Byron Jackson: When I penetrated her... I ended up getting a... cut.

Tammy: He grabs himself. He turns the light on. And I have cut... the top of his penis. I mean, like, what the hell? You know? What's going on? And he's like, "Tammy, you... you've cut me."

Byron: She was confused about it. Just as well as I was.

Tammy: So I'm thinking in my head, "Well, the rest of the mesh."

As a woman, you're thinking, "Am I ever gonna be able to have relations with my husband again?" Was he ever gonna want to stay with me?

Byron: At first, as she's going through her illnesses and everything, you're not thinking about that. But then, you know, we're talking an eight-year period... of not having relationships with your mate. It can be really stressful. That was taken from us.

Tammy: I've had a major surgery... bladder repair... cervix removal... reconstruction.

Byron: Your surgeries, that's a grand total of how many? Oh, Lord. Eighteen? Nineteen? Byonia? What's today's surgery?

Byonia (Tammy's daughter): I don't know. I've lost count.

Tammy: Byonia knows more about mesh than a lot of doctors. She's been through every surgery. I want to be a good wife and I want to be a good mother, and I still cannot do the things I want to do with my daughter.

I have a daughter that says, "I wish." "Momma, I wish we could ride my bike. I wish that I could take your pain." The hardest one to hear is, uh... "Mommy, is it my fault you had mesh?" She's smart enough to know... She's heard women talk. That she knows it is a lot of it from childbirth. That should never be in her heart or her mind. That's my guilt.

Alex Gorsky, CEO, Johnson & Johnson:

"We take our responsibilities as a leader in health care very seriously. We're fortunate to be in an industry where human health care is the basis of our business. And we measure success by improving the quality of people's lives."

Adam Slater, Attorney:

The CEO of Johnson & Johnson is Alex Gorsky. Before he was the CEO, he actually was the head of Ethicon, the unit in the company that these products were sold through. And on his watch, there was a flood of information coming into the company... of women suffering very severe complications.

Adam Slater, Attorney – to Alex Gorsky during a depositions hearing:

When did anybody first make you aware that anybody in the world had a concern about the safety of the Prolift?

Gorsky: I don't recall.

Adam Slater:

Before the pelvic mesh devices even came to market, the surgeons who were developing the prototypes... were telling Johnson & Johnson, "This mesh is not safe." And the director of medical affairs acknowledged it on the record when I took his deposition.

Adam Slater, Attorney – to Dr Piet Hinoul, VP of Medical Affairs, Ethicon/Johnson & Johnson, during a depositions hearing:

"You knew significant retraction could occur?"

Hinoul: Yes.

"You knew that a significant retraction could lead to pain for the patient, correct?"

"Yes."

"You knew it could lead to the need to have subsequent invasive operations to try to either... re... remove or revise that contracted mesh, correct?"

"Yes, sir."

"As you sit here now, are there any risks or adverse reactions, adverse events connected to the Prolift that medical affairs at Ethicon know of that were not known at the time of launch?"

"No. There are no new adverse events that we were unaware of at the time of launch."

Adam Slater, Attorney:

What they did was willfully ignore the risks they were putting these women to without telling them. And actually, not just not telling them, but telling them how safe this was going to be and how wonderful this was going to be, knowing they didn't have a basis to say that.

People who go to work in medical device companies, they're scientists who actually want to do the right thing. But if the science or the medicine isn't jiving with the marketing, the marketing is always gonna win out, always.

In the past decade, mesh lawsuits have cost Johnson & Johnson more than $300 million.

During that time, their revenue exceeded $683 billion.

— Johnson & Johnson Annual Report, 2017

Angie Firmalino, Essure patient:

So, it is December 10th, Sunday. Um, two days before my lumbar puncture spinal tap. My daughter, Rayne, is going to drive me and stay with me there the whole day. I think they said they do the procedure around 7:00 a.m. So, yeah. Yay, spinal tap.

Nurse: Have you ever had any surgeries done?

Angie: Lots.

Nurse: What have you had?

Angie: I had a medical device called Essure – the new female sterilisation.

Nurse: Oh, yeah.

Angie: Those expelled and got migrated in my uterus. I had surgery to remove those, then I had to have a tubal ligation.

Nurse: So, I guess you're not pregnant.

Angie: No, because then, later, I had to have a hysterectomy because of the fragments from the devices that broke.

Nurse: Get out of town!

Angie: Then I had two more surgeries as I wasn't healing from the hysterectomy. So they had to repair the vaginal cuff twice.

Nurse: Holy crap!

Angie: Yeah.

Nurse: Sorry, that's like...

Angie: I've had three joint surgeries because...

Angie Firmalino, Essure patient:

Essure removal is the bane of my existence. We've seen the manufacturer change the removal protocol, contradicting themselves and going back and forth on what's okay and what's not okay. Because of that, a lot of doctors are winging it. And, unfortunately, breaking them, pulling them, cutting them, stretching them. 'Cause, if you pull them or stretch them at all, it'll fragment and leave pieces behind.

This is what happened to me. The device ended up breaking and leaving me with fragments everywhere, which then set off my immune system. Which then set off a connective tissue disorder that started deteriorating my joints.

Bayer has admitted that it causes an autoimmune response in a small percentage of women. Um, however, we don't think it's a small percentage. Women have all these problems that seem to have nothing to do with their pelvic area. So, we started the Autoimmune After Essure group. What's just as crazy as that, we see a really high rate of women that are becoming pregnant after being implanted with Essure. So, we've started a Parents of E-babies group.

We're seeing patterns of health problems with these babies. We have seen the device puncture the amniotic sac and cause preterm labour. We've seen a lot of loss. I've seen women have to bury premature babies. This is devastation. Life devastation.

There have been more than 800 failed pregnancies associated with Essure.

Angie Firmalino, Essure patient:

There's nobody paying attention. We are keeping those records because nobody else is.

Madris Tomes, Former FDA Analyst, CEO, Device Events:

We assume the FDA has the data that they need to crack down on manufacturers that have bad devices or to recall a product, and they don't have that. They don't have that.

Dr David Kessler, FDA Commissioner, 1990-1997:

There is a system for reporting complications... but there's tremendous underreporting, because it's a voluntary system.

Dr Martin Makary, Professor of Surgery and Health Policy, Johns Hopkins School of Medicine:

The FDA has said, "If there's a problem, just come back to us and let us know." Well, that reporting system relies on self-reporting. There are huge problems with self-reporting complications.

Dr Rita Redberg, Editor, Jama Internal Medicine:

If a physician observes an adverse event, they do not have to report it. The only... bodies that are required to report adverse events are the companies. And the industry is not interested in having problems with devices become apparent. It's estimated that only three to four percent of all adverse events... get reported to the FDA.

Dr Adriane Fugh-Berman, Professor of Pharamcology & Physiology, Georgetown University:

A study found that the worse the outcome was, the less likely it was that they would report it to FDA. So we don't know about the adverse effects of a new implant until months or years after it's on the market. By then, that may have been put into hundreds or thousands of people.

Angie Firmalino, Essure patient:

Here's some examples of doctors putting in multiple coils. There's three coils here on this side and one on this side. This one is way, way out of the fallopian tube. Here's one with six devices. The doctors are told by the Bayer reps that come in, who aren't doctors... Reps come into these rooms to sell these devices, and they stand there and watch you get implanted, and, if it misfires and it just gets shot off into the uterus, they just tell the doctor to load up another one and try again. So we're seeing women with five, six, sometimes eight devices, inside of them, when you're only supposed to have one per tube.

Every year, there's an annual ACOG convention. And ACOG is the largest gynaecological organisation in the United States, so there will be thousands of ob-gyn doctors at this ACOG convention. There are so many doctors that still believe there are no problems with this device. Looking at the photos I think changes their minds.

Essure Rally, 2017, ACOG Convention, San Diego, California

Bayer has no data! Do you have malpractice? Bayer has no data! Do you have malpractice? Bayer has no data! Do you have malpractice? Bayer has no data! Do you have malpractice?

Make sure you tell Bayer we're out here. We're not going anywhere. Are you giving warning?

Convention attendee 1: What was the biggest problem with them?

Where do we begin? Chronic inflammation.

Convention attendee 1: Which part?

Uteruses that are swollen, two and three times the size.

It's been in the market for... It's been in the market 15 years.

Surgeon 1: Like I said, I'm putting them in less than I used to. But for some...

You should never put them in.

Surgeon 2: You have two doctors here who've been around long enough to know that there are complications that occur all the time, in all of medicine and surgery. And it's unfortunate. I'm sorry you had to go through that.

Are you aware of all the side effects of Essure?

Surgeon 3: No, if you do a good job, you don't have any problem.

Even if they do a good job... All those women... See that sign? All those names are all hysterectomies and surgeries and salpingectomies. It doesn't matter where they're implanted. They move.

Surgeon 3:No, no, they don't.

We have proof. What happens if there is a complication?

Surgeon 3:: Well, then it goes in the category of people who have complications. You remove it, and that's it.

How do you remove it?

Surgeon 3: You remove it by hysteroscopy. You put it... You... you pull it out? You put an instrument inside, and you pull it out. You pull.

You cannot do that. It breaks.

Surgeon 3: You... you... You are not a doctor. You are working... You are talking like nonsense.

I have 33,000 women in this group...

Surgeon: No, no, no.

...with over 9,000 surgeries. I can tell you that we've had fragments that are unretrieveable. They cannot get them.

Surgeon 3: Okay, guys, nice to talk to you. Okay? Good luck.

Dr Deborah Cohen, Associate Editor, BMJ:

There's a lot of uncertainty in medicine. I think, as physicians, we're not very good at saying, "We don't know," at times. It's fine for you to shout about the benefits or overstate the benefits of a treatment. The minute you raise concerns that something might not be working as well as it should, you are often criticized. You're told you're unnecessarily scaring patients.

Dr Stephen Towers, Orthopaedic Surgeon:

It doesn't seem like doctors are requiring a high level of evidence in order to implant a new device. Yet in order to abandon that device, they're requiring a greater level of evidence than it took them to decide to implant the device. That's turning everything on its head.

Dr Martin Makary, Professor of Surgery and Health Policy, Johns Hopkins School of Medicine:

We attract good people in health care, but there's this tremendous hunger to have the latest gadgets, the newest technology, without the proper evaluation of that technology. So, we shouldn't be surprised when some of the health care goes wrong.

Anonymous current Medical Device Sales rep:

If I knew this business... when I got into it X amount of years ago, I would have done something else. I worked for one of the largest medical device companies in the world. My ultimate job was to make sure that the surgeons used my implants in surgery. It's all about usage. So the more implants you use, the more money they're going to make. It's gotten worse over time because of greed.

Dr Martin Makary, Professor of Surgery and Health Policy, Johns Hopkins School of Medicine:

Most doctors do the right thing and always will to the best of their ability. But some fraction of doctors respond to the perverse incentives of getting paid more for the more you do, regardless of the appropriateness of that medical care. There are kickbacks in the United States today that are entirely legal.

Anonymous current Medical Device Sales rep:

It doesn't have to necessarily be, "Dr. Jones, I'm giving you money." It could be consulting, it could be teaching. It could be providing money for a fellowship program.

Medical Companies paid doctors more than $2 billion in 2016.

– Open Payments CSM

Anonymous current Medical Device Sales rep:

There's some doctors that are good, some doctors that aren't. I had one surgeon recently who said, "You make the best products, but you don't do enough for me, so I'm using somebody else because they do more for me." Welcome to the business.

In days gone by, surgery was all about blood and guts. In the future, surgery will be about bits and bytes.

Is the future already here?

It's a blend of science fiction and medical reality.

The robot will see you now.

Tonight, a story from the cutting edge.

The million-dollar Da Vinci system, a revolutionary tool for surgeries of all kinds.

Dr Catherine Mohr, VP of Strategy, Intuitive Surgical:

The Da Vinci is a large, fairly complicated robot able to bring a camera and instruments in together through one small tube. The Da Vinci is able to reach anywhere. Very exciting to think where we get to go with this.

Dr Martin Makary, Professor of Surgery and Health Policy, Johns Hopkins School of Medicine:

Da Vinci allows us to do remote surgery from about seven feet away from the patient. We work in a remote-control console, sort of like a video game machine. We look on the screen, at the image from inside the abdomen. And we can perform the operation with remote control hands.

Da Vinci, by Intuitive Surgical. They're now in 64 countries.

Intuitive is absolutely the dominant market leader in this field with a turnover last year of over $2 billion.

Dave Rosa, EVP of Scientific Affairs:

We're an innovative company. We will continue to innovate, put new products out.

Gary Guthart, CEO Intuitive Surgical:

Intuitive is motivated by the opportunity to invent new things, create the future.

Dr Catherine Mohr, VP of Strategy, Intuitive Surgical:

That is my vision for your future. Thank you.

Dr Martin Makary, Professor of Surgery and Health Policy, Johns Hopkins School of Medicine:

The story of how the robot came into health care is the story of what's wrong with medicine in America today. Massive adoption of a new technology with little evaluation of the outcomes.

The Da Vinci robot was marketed with a strategy of approaching doctors and communities and telling those doctors, "We can help drive business to you. We can market you as the robot doctor."

The robot is better for certain operations. But in many situations, it provides no benefit to the patient, and it may add operation time and it may add some risks.

Da Vinci Surgery Promo: Hysterectomy for Benign Conditions:

"You need surgery." Three words no one wants to hear. This video will explain your surgical options for a hysterectomy...

Dr Steven McCarus, da Vinci OB/GYN Surgeon:

Hysterectomies are a very high-volume, common procedure in the US. About 500,000 women have their uterus removed every year.

Da Vinci Surgery Promo: Hysterectomy for Benign Conditions:

During a hysterectomy, doctors remove part or all of the uterus, the cervix, both fallopian tubes, and both ovaries. The surgeon then stitches the internal opening closed. If you're told you need a hysterectomy... ask your doctor about Da Vinci surgery.

Debra Rybos, da Vinci hysterectomy patient:

I had a biopsy, and it came back positive for, um, endometrial cancer.

Julie Daily, da Vinci hysterectomy patient:

I was having a lot of female trouble, a lot of ovarian cysts.

Astarre Gudino, da Vinci hysterectomy patient:

They sent me for a vaginal ultrasound because we couldn't figure out why my blood counts were so low, and I had a tumour.

Vicki Mills, da Vinci hysterectomy patient:

I was diagnosed with uterine cancer. I actually was kind of happy, because I said, if I have to have cancer anywhere, that's the place to have it, because I can have it taken out.

Julie Daily, da Vinci hysterectomy patient:

The doctor recommended a hysterectomy. And the only type that he said he did was the Da Vinci.

Mary McNulty, da Vinci hysterectomy patient:

He said, "Well the best way to do this, the fastest way and the quickest recovery would be to use the Da Vinci robot."

Lori Shanyfelt, da Vinci hysterectomy patient:

It just sounded like the newest, greatest thing, and I had no reason to believe otherwise.

Intuitive Surgical initially submitted the da Vinci robot to the FDA's stricter Pre-Market Approval process.

An FDA manager intervened to clear it through the 510(k) process instead.

— Taylor v Intuitive Surgical, Inc.

Richard Friedman, Attorney

Originally, Intuitive Surgical told the FDA that a huge amount of training would be provided as part of the sale of the machine to the hospitals, but shortly after the FDA gave permission to market, Intuitive scaled back all of the training requirements. And the reason is, if they said, "Your surgeons can use it, but they need nine weeks of training," no one's gonna buy the machine. So, you have surgeons who operate for half a day on pigs, take a ten-question multiple-choice test, and have a proctor, another surgeon, watch them do two surgeries, then they're turned loose with the machine.

Dr Robert Poston, da Vinci Cardiac Surgeon:

I was told that it takes ten cases to get good at robotics. But I know now, in retrospect, that I didn't really start to feel comfortable until I was about 200 or 300 cases. In other words, that area where you'd call yourself proficient.

Dr Steven McCarus, da Vinci OB/GYN Surgeon:

The surgical robot in inexperienced hands adds complication or injury rates to the patient. A lot of surgeons that shouldn't be using it are using it. That's the problem.

Da Vinci Hysterectomy Patients

Julie Daily, da Vinci hysterectomy patient:

So, I had the hysterectomy, go home. I'm thinking, "Wow, this is smooth, easy." Within a day or two, I was running up and down the stairs.

Michelle Zarick, da Vinci hysterectomy patient:

And then a couple of weeks later, I started to not feel so great.

Debra Rybos, da Vinci hysterectomy patient:

I was getting up in the morning, I sat down to go to the bathroom, I felt all this pressure. I looked down and this huge... pomegranate-looking thing was protruding from my legs.

Lori Shanyfelt, da Vinci hysterectomy patient:

I think I was actually at my clothesline, putting something... I think I'd washed a load of sheets, and I heard a pop.

Julie Daily, da Vinci hysterectomy patient:

I go to the restroom and I feel something emerge from my vagina.

Vicki Mills, da Vinci hysterectomy patient:

A whoosh of liquid came out. And now there was about three inches of my insides coming out of me. I thought I was gonna throw up. And when I did, I heaved... and my intestines came down like halfway to my knees.

Julie Daily, da Vinci hysterectomy patient:

I had three feet of my colon fall out. It's in the documentation. So... I get a towel... and hold it in. I run in there, fall out on the floor, and my husband's like, "What's wrong?" I said, "My colon's fallen out." He said, "Let me see." He saw and then he totally had a nervous breakdown.

Vaginal cuff dehiscence occurs three to nine times more often with robotic surgery.

— Uccella, Ghezzi, Mariani, et al., 2011

Da Vinci Hysterectomy Patients

Julie Daily, da Vinci hysterectomy patient:

Then, when I got to the hospital, they didn't know what to do. They were freaking out. They'd never seen it.

Astarre Gudino, da Vinci hysterectomy patient:

I get to the emergency room, and I remember thinking so clearly that I was dead, like this was it.

Mary McNulty, da Vinci hysterectomy patient:

They had to call the specialist, and he said, "I don't even know if the surgery... I can't say if it'll... save her now. I'll do my best." I have nightmares about it all the time where I think I'm on that table, going into the operating room. You know, just terrible, terrible memories of it, and it just never seems to leave me.

Lori Shanyfelt, da Vinci hysterectomy patient:

It's been... what, three years? And I still have... problems.

Vicki Mills, da Vinci hysterectomy patient:

I have had to give up a dream of ever having a partner, of ever being intimate again, because, to me, um... penetration means death.

Astarre Gudino, da Vinci hysterectomy patient:

It changed the full direction... of my life.

Lori Shanyfelt, da Vinci hysterectomy patient:

It's taken my life away. I'm sorry I ever heard the word Da Vinci. And then, like I said, every time that I... hear of more injuries, it just rubs salt in the wound.

Intuitive Surgical continues to advise surgeons to determine for themselves if they're ready to perform robotic surgery.

— Intuitive Surgical, da Vinci Training 2018.

Ana Fuentes, Essure patient:

After three years of bleeding, I ended up having a hysterectomy. And no more bleeding, but the pain is still severe. The pain that I had sometimes prevented me from going to work. And eventually, I lost my job. I had to do this car wash because I haven't worked for a month. My doctor just put me on disability... which could take months. So, I'm out of income right now.

I can't afford my rent right now. So, I have to move out, and if I don't find a place, and without income and proof of income, I can't get an apartment or anything, so I'm scared I'm gonna have to be split with my kids.

Ana's kids: Ever since 2011... we've moved around a lot. I don't think we've had one place that was stable. Ever. We don't know where we're going to be at school. Because we're gonna get another house, and I don't know where that house is gonna be. My mom can't keep a job because she has to go to the doctors a lot 'cause she gets sick a lot, and it's just... It ruins her opportunity of having a job. It makes me feel sad that my mom is at the hospital.

Interview with Peter and Angie Firmalino, Essure patient:

Peter: It's tough, watching her not be able to do stuff. That much more I have to do. We used to do it together.

Angie: I suck now. I'm just cranky and miserable, in pain all the time. I'm not fun. I can't drink, I can't dance, I can't do anything. Well... But at the same time... You know, I'm so grateful for what we have. We have great kids and a great house, and we have each other and... we're alive.

How does it affect your love life?

Peter: Oh... Oh, God.

Angie: It was terrible for a while. –

Peter: Yeah.

Angie: There was no love life.

Peter: No.

Angie: When I... With all the surgeries and stuff. But even when I first had it in, it was painful. Yeah. That part of our life has been ruined permanently.

Peter: It's hard.

Angie: Yeah, you don't... I don't think it ever goes away. I don't think it ever will. It's sad because I have seen other people's relationships die in the group. I've seen a lot of women whose husbands have walked out - over the intimacy... the lack of intimacy. I've seen women suicidal, women losing their families and... thinking that there's no reason to stay alive.

Peter: I think it's amazing what she's done... to help these women. Facebook is a full-time job for her now, basically. She wakes up in the morning... She's a very determined person. She gets something in her head, and that's it.

Gaby Avina, Former Essure Spokeswoman and Essure Patient:

I started getting random messages in my Facebook... from women who started connecting me with the Gabriella Avina that was the spokesperson, the Ask Gaby. They found me... and said, "Are you the Gaby that was speaking for Essure? Will you talk to us?" And finally... uh, probably about a year of them trying... one of them said, "Can you just tell me how your health is?" And then I listened.

I was fatigued. I was tired all the time. Then I started falling. Just... My legs would give out. The doctor said it was an immune response to something. My story was similar to so many others. All of a sudden, it all made sense. If only they'd been honest with me from the very, very beginning.

Essure promo videos:

The Essure procedure can be performed in your doctor's office and is over 99% effective.

It's 99.74% effective.

It's 99.8% effective.

It's over 99.95% effective.

Dr Scott Sills, OB/GYN

It really wasn't tested for a sufficient amount of time. Most patients that had the Essure device were followed for about 12-18 months, and the manufacturer reported very satisfactory results from it. But for a product that's supposed to be a lifetime implant, to cut off the study window at about a year and a half left a lot of questions unanswered.

Gaby Avina, Former Essure Spokeswoman and Essure Patient:

I was part of the clinical trial, and no one asked me, "Are you feeling sick? What is your health like?"

Essure promo videos:

Almost all women who participated in the clinical studies rated their satisfaction with Essure as good, very good or excellent.

Kimberly Hudak, Essure Clinical Trial Patient:

The first time I saw the question, "Rate your comfort of wearing the device," I said, "What does this mean? I'm not wearing anything. This is something that's implanted inside of my body." The nurse said, "Can you feel it?" I said, "I can feel pain in my abdomen. Where that pain is coming from, I don't know." And she said, "Then you need to rate it as excellent."

They would say, "Are you happy with the product?" I would say, "No," and they would say, "But you're not pregnant?" I would say, "Correct." "Well, then it's doing its job, so you have to be happy with that."

The most striking thing is they'd crossed out answers and changed them. Where it said I was having pain, they'd crossed it off and said, "No pain reported." When I questioned Bayer about it, they said this is absolutely customary in a clinical trial.

Women with Essure experienced sterilisation failure seven times more often than women who had their tubes tied.

— Bouillon, Bertrand, Bader et al., 2018.

Jeanne Lenzer, author of The Danger Within Us:

It turns out that the vast majority of research is not coming from an objective source.

Dr Adriane Fugh-Berman, Professor of Pharamcology & Physiology, Georgetown University:

It used to be that about 70% of biomedical research was funded by the government. In the last 20, 25 years, that's changed. Now about 70% of biomedical research is funded by industry.

Jeanne Lenzer, author of The Danger Within Us:

They're paying for the research, so naturally we're going to get the results that they want to share.

Madris Tomes, Former FDA Analyst, CEO, Device Events:

So, devices can be on the market for years and cause many deaths, many injuries before it becomes public.

NBC News Investigates broadcast:

A medical device implanted in thousands of people that is linked to more than two dozen deaths...

During emergency open-heart surgery, doctors removed this one-inch piece of metal.

It floated in front of our eyes, literally, first into the right atrium and then into the right ventricle.

ABC15 Arizona exclusive broadcast:

Major health concern over breast implants. They could cause a rare form of cancer. It may cause other illnesses too.

The Denver Channel 7 ABC Broadcast:

When she had hers taken out, they found mould inside, and she's not alone.

ABC News broadcast:

Two dead, 179 exposed to a dangerous superbug. A piece of medical equipment may be to blame.

CBS This Morning Broadcast:

A device called a morcellator as used to shred fibroid tumours so they could be easily removed. The shredding ended up inadvertently spreading the cancer.

CBS News broadcast:

A defibrillator was withdrawn from the market after 13 deaths were linked to wiring problems. The FDA approved this device but did not require testing in humans.

We can no longer rely on the medical device companies to do what's in the best interest of the patient. And we can no longer rely on the FDA to properly regulate these devices.

Dr Julian Nicholas, Former FDA Scientist:

I was at the Food and Drug Administration from 2006 to 2009. I was the lead gastroenterologist of devices. I think I cleared, or was involved in the clearance, of over 250-odd devices.

I think the vast majority of doctors and scientists at the FDA... do their best. They do it with integrity, honesty.

In mid-2009, a file came on my desk to look at this CT scanner; this device that affects many millions of people in our country.

Dr Rebecca Smith Bindman, Professor of Radiology and Biomedical Imaging, UCSF:

A CT scan takes the equivalent of hundreds and hundreds of X-rays while a machine rotates around your body. They're an incredibly good test for diagnosing a range of diseases that gives you very sophisticated 3-D images. But the doses of radiation that we use day in and day out for CT are in the range that we know it will cause cancer in some people. And yet, the use of CT scanning has quadrupled in the last 15 years.

CT scan overdose and overuse gives 50,000 Americans cancer every year.

Korley, Pham, Kirsch, 2009.
Gonzalez, Mahesh, Kim, et al., submitted for publication
Smith-Bindman, Theis, Marlow et al., submitted for publications

Dr Rebecca Smith Bindman, Professor of Radiology and Biomedical Imaging, UCSF:

The elephant in the room is it's a very profitable part of the health care system. It's a way a lot of radiologists, emergency departments, hospitals make money.

Dr Julian Nicholas, Former FDA Scientist:

There's a lot of excess use of this device, and so I simply said, "We should have a warning on the FDA label just to warn the doctor... and therefore the patient, that actually if you use this device... and certainly if you use it repeatedly... your risk of cancer or developing abdominal cancer will increase.

I couldn't believe the pushback I'd got from managers with no medical experience.

There was a group of FDA physicians who were very concerned about the way products were being cleared and approved. We took these concerns up the chain of command to Jeffrey Shuren, the director of the Center for Medical Devices at FDA. And what did he do? He not only did nothing, he took it one step further. He retaliated against people.

Dr Ewa Czeiska, Former FDA Scientist:

Once we started complaining... FDA put their spy software in our computers. And they were monitoring all our activities.

Dr Julian Nicholas, Former FDA Scientist:

The FDA installed what's called Spector software onto a number of physicians' and scientists' computers, and it allowed them to capture screenshots every two seconds... and keystrokes. It's as if to say their own doctors are somehow criminals for exposing... a public health issue.

It left a tremendous chill amongst the FDA scientists.

Within two years, all nine FDA scientists who spoke up about safety concerns were fired or let go.

A Congressional investigation found the FDA ordered the spying to retaliate against the whistleblowers.

— United States Congress Joint Staff Report, 2014

Scott Whitaker, CEO, Advanced Medical Technology Association:

Listen, safety's as important to us as it is to anybody else. None of us want a product on the market that's not safe, right? But that's why we rely on regulators to help us get there. I think the US regulatory system works well. It's robust, it's thorough, and it's been very effective.

Jeanne Lenzer, author of The Danger Within Us:

The device industry is very well represented by their main lobbying group, AdvaMed.

Scott Whitaker, CEO, Advanced Medical Technology Association (addressing the Global Summit for Medical Technology):

Good afternoon, everyone, and welcome to the Global Summit for Medical Technology. This is a room full of disruptors. We are risk-takers of the highest order. Not enough Americans understand the important role we play, or frankly give us enough credit for the innovation we bring. Sure, we'll pay attention to Washington. That's my job. That's what I do. But we have more power in this room than most governments around the world. We have the ability to create jobs and prosperity... to open and expand markets and unleash innovation. Let's show the world that we are what's next.

AdvaMed and its member companies spent more than $64 million on lobbying in 2017.

— OpenSecrets.org

Dr Michael Carome, Director, Public Citizen Health Research Group:

They have lobbied hard to see the standards for approval of devices watered down over the years.

Jeanne Lenzer, author of The Danger Within Us:

Device companies unleash armies of lobbyists in order to influence politicians. And these politicians are vulnerable. They don't know science. It's often very flowery and impressive language about how they put patients first and they want only the best.

Scott Whitaker, CEO, Advanced Medical Technology Association:

We want to make sure that new medical innovations get to patients and help save lives, improve the human condition, eliminate suffering, and make this world a better place, that's what we all agree on, right?

Lee Fang, Journalist, the Intercept:

The medical device industry has incredible levels of influence in Washington, D.C. They have provided dark money contributions that are used to secretly fund political campaigns. Medical device companies also fund think tanks and patient advocacy groups that can go to Congress and make the case for them.

Jeanne Lenzer, author of The Danger Within Us:

Perhaps an even worse problem is the revolving door. A number of FDA officials have both come from industry and then go back to industry after they're at FDA.

Dr Diana Zuckerman, President, National Center for Health Research:

When they go to work for the companies, they can tell the companies all the tricks of how to get around FDA regulations, how to get what you want. Almost all the heads at the FDA went on to work for industry.

Commissioner Henney, 1999-2002: served on the boards of six medical companies since leaving the FDA.

Commissioner McClellan, 2002-2004: served as board member or advisor for eight medical companies since leaving the FDA.

Commissioner Crawford, 2005: convicted of falsely reporting he did not own stock in medical companies while at the FDA.

Commissioner Von Eschenback, 2006-2009: served on the board or worked for twelve medical companies since leaving the FDA.

Commissioner Hamburg, 2009-2015: married to a hedge fund CEO who invested in medical companies while she was commissioner.

Commissioner Califf, 2016-2017: Began working for a medical device company less than a year after leaving office.

CNBC News Broadcast:

President Donald Trump says he's picked a nominee to run the Food and Drug Administration. Dr. Scott Gottlieb is a popular choice in the pharmaceutical industry. "Thank God it's Gottlieb," said an investment analyst at Robert Baird. Why would they have that reaction? They were breathing a sigh of relief. He's a known entity in the industry.

Scott Whitaker, CEO, Advanced Medical Technology Association:

I've known Scott [Gottlieb] for a long time. He took that job because he wants to do what's in the best interest of the American people and the agency, and not what's in the best interest of anyone else.

Lee Fang, Journalist, the Intercept:

Gottlieb has been a consultant to a range of medical industries. He's also worked at a venture capital firm that actually specializes in investing in start-up medical device companies.

Dr Scott Gottlieb, in FDA Commissioner Confirmation:

I'm proud of my relationship with New Enterprise Associates. It's been one of the premier venture capital firms in the country, starting a lot of innovative ventures. Over the time that I was there, they invested about $14 billion in 500 different companies.

Gottleib's company, New Enterprise Associates, funded the development of Essure.

— New Enterprises Portfolio

Senator Elizabeth Warren, in FDA Commissioner Confirmation:

You have spent your life entrenched in the companies that would benefit from looser regulations. But I think it raises the very real question of whether someone who seems to oppose the FDA's basic safety mission should be running the agency.

Gottleib agreed to recuse himself from decisions regarding companies he has been involved with for his first two years in office.

— US Department of Interior Ethics Pledge

Scott Whitaker, CEO, Advanced Medical Technology Association:

I can tell you he doesn't have any bias as a result of that. I've never seen it and don't expect to see it, knowing him the way I do.

One of Gottleib's first acts was to hire a new lead attorney for the FDA. He chose someone whose previous job was representing Bayer against patients harmed by medical devices.

— US Food & Drug Administration

Jeanne Lenzer, author of The Danger Within Us:

The FDA is supposed to protect the public interest. Unfortunately, their behavior shows that they have been captured by industry.

Scott Whitaker, CEO, Advanced Medical Technology Association (addressing he Global Summit for Medical Technology):

Scott, thank you for coming across the country to participate with us at this conference. I speak,I think, for the entire industry. Where we were five years ago at the FDA compared to where we are today is night and day. And I think your leadership has made a huge difference and we are really grateful for that.

Dr Michael Carome, Director, Public Citizen Health Research Group:

In 25 years, we will, I think, be worse off. All the legislation we're seeing, again, driven by lobbying from industry, is moving in the wrong direction and there's no evidence that's gonna shift.

CNBC News Broadcast:

I just came out of a briefing with senior officials at the White House about the executive order that President Trump will sign this morning.

President Trump:

We issued an order which says, for every one new regulation, two old regulations must be eliminated.

Dr David Kessler, FDA Commissioner, 1990-1997:

"Regulation is bad. Let's cut regulations. For every regulation, we're going to cut umpteen regulations." That bravado... may apply to certain fields, but it can't and shouldn't apply when you're talking about putting a device in someone's body.

President Trump:

We're very proud of this one.

Essure Patients

Ana Fuentes, Essure patient:

I'm gonna leave. I need to go find a place. We are going to go try to find a hotel that will take us all in with a reasonable price. And call it a day, I guess.

Ana's child: Mom, there's a homeless over there.

Ana: I know, baby. You see, girls? It could always be worse. He probably doesn't have a car or anything and we do have a car.

How much is it for a two-bed? 110 for one night? Do you have weekly discounts or anything like that?

Nothing right now.

Give me a second, okay? So, it's 110.

110 and a private room. –

Are you guys happy? It's really tiny. So, I guess we're home. For a night.

Essure Patient Advocates Meeting, Sacramento, CA:

I want to thank everybody for coming. It's just amazing to finally see all of you. So, let's start off by maybe just going around, just say who you are and where you're from.

My name is ***Alicia Perry***. I am from Stockton. I am an implantee, I'm just going to say it, for ten years. No longer. And I'm so glad to see everyone here. Thank you.

I'm J***uanita Nunez-Archuleta***. I'm an admin on the Spanish page and I am E-free, seven months.

I'm ***Gaby Avina*** and I'm from Martinez, California. I was one of the clinical trial participants, so I had mine implanted in 2000, and I had mine taken out in 2014. I don't know if any of you were familiar with the Ask Gaby website... that was on Conceptus and Essure's website. That was me. I was a spokesperson. I failed thousands of women for seven years. It's a long time to tell women that a product is great. So, the guilt that you live with... and the pain... and just crazy feelings of responsibility because of that.

Thank you for being on this side now because it's important that people now see the damage and more and more doctors are starting to see it. Very validating.

Angie Firmalino: We just want to have a discussion and brainstorm. What should our new media push be right now?

Gaby Avina: I felt good about it 'cause I saw women that came together to fight for what they believe in. They're strong, they're smart women, and they're getting the media to listen.

ABC2 Investigators Broadcast:

It was supposed to be safer and less invasive.

Well, why are so many people complaining about a popular birth control device?

"Pain, back pain."

"It was debilitating. I could barely walk."

"I never thought I would be looking at a hysterectomy... at 29."

"My body is just devastated."

Damaged, they say, by a birth control device called Essure.

"The stories started getting out in the news and then other news stations started seeing the other stories and were like, "Okay, let's do this in our area." "

Five heart-wrenching stories of extreme physical pain.

Six women with severe medical problems. Thousands of women like Becky are sharing their experiences on Facebook.

Angie Firmalino, Essure patient:

There are now 35,000 members in the group. We've set up groups in other countries. We found women in Italy, willing to take over the page. We started the Netherlands group. We had women from France. They're all branches of us. So, we've got 11 subgroups that are other countries.

YS your stories Broadcast:

Now, a controversial birth control device in the US is going off the market in Europe.

Bayer announced it is pulling out of the European market due to a lack of interest. But a spokesperson says, "Bayer's decision does not impact the sale or marketing of the product in the United States where there continues to be demand, despite the recent inaccurate and biased reporting."

Angie Firmalino, patient:

That's bullshit.

The equivalent of the FDA in Europe asked Bayer to provide more safety data. And Bayer, at that point, decided to withdraw it from the market. It's very frustrating.

Our group has been fighting in our country for the longest. Yet we're the ones with it still on the market.

Bayer has no incentive to take it off the market here. Nobody's holding the manufacturer accountable.

We're not gonna stop until it's off the market.

The FDA isn't doing anything, the manufacturer's not doing anything. We need to push Congress to force the hand of the FDA.

Illinois Representative, Jill Schakowsky:

So, this device is still being inserted in women?

Angie: In the United States...

Jill Schakowsky: In the US?

Angie: Because September 18th, it came off the market everywhere else in the world. Look at how far up the injury and death reports go now. Because they're not being held liable, they don't have any incentive to take these devices off the market. People are just getting harmed and injured, and nobody's doing anything about it.

Other woman: We have many, many women who are ending up with fragments and massive issues and re-surgeries.

Jill Schakowsky: Women just seem to be expendable.

Other woman: Yes. That's how we're starting to feel. We're disposable.

Angie: The FDA has been very clear that they're not going to take this off the market. That this is the manufacturer's responsibility.

Jill Schakowsky: I know of no possible reason, when they are chosen to protect the health of the people of this country, that they would choose to go in the other direction and protect the manufacturers. That's gotta be changed.

Connecticut Representative, Rosa DeLauro:

I wanted to get as much information as I can with the various personal stories. I don't know how many of those that you have.

Essure patient: A lot.

Essure patient: Thousands.

Essure patient: Tens of thousands.

Rosa DeLauro: Tens of thousands, okay. This place works with good people on the inside trying to manoeuvre and push legislation forward. The way it really works is the external pressure. And that's all of you and you are in great numbers out there. Welcome to the NFL.

You just cannot get tired. It is a continuous effort.

Angie: We won't stop. They've already taken away my health. What else can they take from me? I have nothing to fear from them. This has to come to an end. I don't know how anyone with a conscience and any sort of compassion could let this continue to happen.

The Congresswomen helped the Essure patient advocates secure a meeting with FDA Commissioner Gottleib in February of 2018.

They presented him with years of data and asked him to remove Essure for the market.

Two months later the FDA required doctors to state the risks of Essure to patients.

The FD allowed Essure to remain on the market in the US.

Couples discussing the impact of pelvic mesh on their lives:

Mesh injured patient's husband: "I go to work... and I'm at work... and those issues aren't with me... until you think about it and think about it for an extended time. We're insulated from... the horror."

Mesh injured patient: "It's the first time I've really heard him say that much detail about how he feels about what we're feeling."

Tammy Jackson, surgical mesh patient:

"It's hard for the men to talk about. This is a safe place for us… I've probably talked to close to... I can't even begin to think of the number of women that have called me. And the only good thing is knowing that I'm not alone."

Tammy and Byron run a support group for mesh survivors and their partners.

Four states are suing Johnson & Johnson for concealing the dangers of vaginal mesh.

Health Watch USA Conference 2017, Lexington, Kentucky:

Dr Stephen Tower:

The take-home message today is that systemic cobalt poisoning from a hip replacement... is a common problem. You could make a strong argument that everyone would be better off if we stopped innovating in total hip replacement and stuck with what's been around for 30 years, and we know there's designs...

Dr Tower has begun presenting his findings to medical organisations around the country.

He cautions that his initial results need to be confirmed by additional studies.

After moving out of her apartment, Ana [Fuentes] left her children with a church affiliated foster family.

She continues to struggle with her health.

The FDA, Bayer, Johnson & Johnson and Intuitive Surgical all declined to be interviewed on camera for this film.

In a written response, the FDA said: "The benefits of Essure outweigh its risks."

Nearly 12,000 adverse events regarding Essure were reported to the FDA in 2017.

In a written response, Johnson & Johnson said: "your assertion that our 'vaginal mesh and hip products have had a negative impact on the health of patients' is untrue."

Johnson & Johnson is currently being sued by more than 65,000 hip and mesh patients.

SAFETY PRECAUTIONS

Research any device that will be used on or in you. New is not necessarily better.

Get a second opinion for any risky or expensive procedure.

Ask your surgeon how many procedures he or she has performed.

Have a friend or family member be your advocate while you're in the hospital.

To see if your doctor has been paid by a medical device company go to openpaymentsdata.cms.gov

Shortly after the premier of this film, Bayer announced with would stop selling Essure in the US at the end of 2018.