What did my Dutch colleague do? She took a net for oranges, like this one here, and said that she went to notified bodies, those issuing the European Community certificate for medical devices. She said: "This is like the net that is implanted inside a woman’s body to contain prolapse after childbirth: can you certify it?” And they believed her. If you can watch a report on global health tonight, an extraordinary report, it is thanks to the brilliant idea of this Dutch colleague. The report was shot with the contribution of the International Consortium of Investigative Journalists, 252 journalists, belonging to 59 newsrooms from 36 countries. Report has exclusive rights for Italy with its partner L’Espresso. And we’ll be talking, for the first time, about a world, that of pacemakers, heart valves, hip replacements, and insulin dispensers. They are very useful and known as medical devices: they make our lives longer, they make us live even better. But, in some cases, they were approved very quickly and caused accidents. In an ever-expanding market, multinationals set the tune. This market is worth $400 billion a year. So let's talk about it by starting from the TAVI heart valve. Behind it, are the multinationals Medtronic and Edwards: they are backed by the big investment funds Blackrock, Vanguard and Wellington. Obviously, their minds are set on reaping dividends. This does not always coincide with the best interest of patients. To develop, certify and implant their product, however, they need Trojan horses. They are thoroughbred horses, but all too often they take off their surgeon’s coat to wear the white collar of a shareholder or businessman. What you're going to see tonight is tough and rigorous journalistic work. The report is by our reporters Giulio Valesini, Aldo Ciccolella and Simona Peluso.

Munich, August 2018: 32,000 healthcare professionals from all over the world are here for the European Society of Cardiology conference. The doctors are discussing new therapies. The sponsors are somewhere separate but not far off: they are the multinationals that produce medical devices for the heart. They pay to be there and showcase their flagship products.

The distance between these two points is 6 millimetres. Our device needs a space of 3-4 millimetres. Do you want to try it?

A few weeks later, they’re back together in London. This time the conference is organized by the community of interventional cardiologists, but the scene is the same. As they eat, they discuss the new frontiers of medicine.

We're here to get the doctors involved, to have them touch the devices.

And if they're interested, can they have their hospitals buy them?
CAJETAN VON KÖNIG - HEAD OF HEART VALVE MARKETING AT BOSTON SCIENTIFIC

Yes, there is a corner where we do business consulting and explain how to get the products at the cheapest price. During conferences, we present the studies on our devices.

SIMONA PELUSO
Do you fund them?

CAJETAN VON KÖNIG - HEAD OF HEART VALVE MARKETING AT BOSTON SCIENTIFIC

We fund them.

SIMONA PELUSO
And do you pay the travel expenses to get the doctors to come to conferences?

CAJETAN VON KÖNIG - HEAD OF HEART VALVE MARKETING AT BOSTON SCIENTIFIC

In Europe, we cannot directly sponsor the travel of doctors. We give money to the organizers who then pay the expenses to avoid influencing anyone.

GIULIO VALESINI OFF SCREEN

Among the stands stand out those of the multinationals of medical devices. Medtronic, the number one in the world. In 2017, it had a turnover of $29 billion. Right next to it is Edwards Lifesciences, with a turnover of $3 billion a year. For some years now, the industry's spearhead has been TAVI, a valve for the treatment of aortic stenosis: one of the most common heart diseases in the world among people over 70 years of age. They make you try to insert it in a sort of video game. It's a revolutionary procedure: the alternative to surgery and if there are no complications, in a few days you're home.

CARMELO SGROI - CARDIOLOGIST, FERRAROTTO HOSPITAL - CATANIA

The lady's awake. If I were to call you... Excuse me a moment. Good morning!

PATIENT
Good morning.

CARMELO SGROI - CARDIOLOGIST, FERRAROTTO HOSPITAL - CATANIA

How's it going?

PATIENT
Good.

CARMELO SGROI - CARDIOLOGIST, FERRAROTTO HOSPITAL - CATANIA

All right. This is a very elastic valve so it adapts very well to the patient's anatomy. With this anatomy the risk of valve rupture because our new device is too large is reduced to a minimum. Through this cannula, we can cross very calcified, very narrow peripheral arteries. This has partly reduced vascular complications.

GIULIO VALESINI OFF SCREEN

Before TAVI, there was only one solution to treat stenosis: place a mechanical valve with open-heart surgery. The result is guaranteed for 16 years. With TAVI, on the other hand, a new valve is placed inside the sick one, delivering it with a catheter. It
is a procedure that has the advantage of being less invasive: but some doctors have doubts about long-term performance.

LORENZO MENICANTI - SCIENTIFIC DIRECTOR AT SAN DONATO GENERAL HOSPITAL
This is a TAVI. This is a valve that has been removed.

GIULIO VALESINI
What was the problem?

LORENZO MENICANTI - SCIENTIFIC DIRECTOR AT SAN DONATO GENERAL HOSPITAL
It wasn’t working anymore because it was all calcified and so it needs to be changed.

GIULIO VALESINI
After how many years did this one become like this?

LORENZO MENICANTI - SCIENTIFIC DIRECTOR AT SAN DONATO GENERAL HOSPITAL
After six years. The patient was operated at 74 years of age and we operated him at 81.

GIULIO VALESINI
The patient, at 74 years of age, was deemed inoperable, so a TAVI was placed; seven years later a normal surgical valve was opened and implanted.

LORENZO MENICANTI - SCIENTIFIC DIRECTOR AT SAN DONATO GENERAL HOSPITAL
That’s right.

GIULIO VALESINI
So this what a TAVI becomes like?

LORENZO MENICANTI - SCIENTIFIC DIRECTOR AT SAN DONATO GENERAL HOSPITAL
This is a TAVI gone bad, for sure. A new method is applied, the long-term effects of which are not fully known. This is beyond dispute.

GIULIO VALESINI
And that's probably why..

LORENZO MENICANTI - SCIENTIFIC DIRECTOR AT SAN DONATO GENERAL HOSPITAL
This application occurs in high-risk patients who have a relatively short life expectancy.

GIULIO VALESINI
It had to be so..

LORENZO MENICANTI - SCIENTIFIC DIRECTOR AT SAN DONATO GENERAL HOSPITAL
It had to be so. I mean, if I put a TAVI in someone who's 90, that's totally justified. Thinking of putting a TAVI in a 60-year-old, that's very disturbing
GIULIO VALESINI
And that happens, though.

LORENZO MENICANTI - SCIENTIFIC DIRECTOR AT SAN DONATO GENERAL HOSPITAL
Yes, sometimes it happens.

GIULIO VALESINI OFF SCREEN
The valve is inserted through a guide, which starts from the patient's femur. But to make it slide it is crimped, i.e., compressed, and then expanded once placed in the aortic valve. The Canadian cardiologist Danny Dvir has been implanting TAVI devices for years. In 2016 he published a study on durability: after eight years, 50% of TAVI devices show signs of degeneration.

DANNY DVIR - CARDIOLOGIST, UNIVERSITY OF WASHINGTON MEDICAL CENTER - SEATTLE
In elderly patients, TAVI degeneration is much slower than in young patients. Degeneration is caused by two problems. One is linked to crimping, which can affect the device's operation. The other is that when we implant it we do not clean the aortic valve from the calcium fragments already present and therefore we risk making that area subject to thrombosis. At the beginning, they were looking for a safe procedure to allow patients in serious conditions to survive for a year. Maybe we need something different today.

GIULIO VALESINI
So if someone is 50, he or she comes to you..

DANNY DVIR - CARDIOLOGIST, UNIVERSITY OF WASHINGTON MEDICAL CENTER - SEATTLE
I'd put a surgical valve in.

GIULIO VALESINI OFF SCREEN
The valve's inventor is the American doctor Martin Leon; he thinks the turnover will rise to $5 billion.

MARTIN LEON - COLUMBIA UNIVERSITY MEDICAL CENTER - NEW YORK
We had some very old patients and they couldn't be operated on. We wanted to give them an alternative.

GIULIO VALESINI
You want TAVI to become the standard for everyone, even younger patients.

MARTIN LEON - COLUMBIA UNIVERSITY MEDICAL CENTER - NEW YORK
We realized that the procedure could be extended and we are doing clinical studies. In coming years, TAVI could become the cure for all patients with aortic stenosis, even younger ones. We're studying to see if the cases of thrombosis are linked to the valve or not.

GIULIO VALESINI
Are there studies that show that TAVI lasts more than five years and that it is not subject to degeneration?
So far we've only had data for five years. The first patients were very old and unfortunately they died; but we're doing new studies and soon we'll have the results. TAVI devices, however, are made just like surgical valves, I don't see why they should last less. And if they really do stop working, we can always add another TAVI inside the valve to extend its life.

Leon, with his French partner Alain Cribier, sold Edwards the patent for the first TAVI valve for $125 million. Leon collected $6 million immediately from the transaction. Edwards promised the various shareholders a total of $30 million linked to the achievement of certain targets.

You sold a company with the TAVI patent to Edwards, is that correct?

That company was sold to Edwards and all the founders earned a fair amount for the shares they had.

Were you also the lead investigator on Edwards' behalf for the TAVI's approval by the FDA? Isn't there a conflict of interest, Professor?

In 2007, when I became the lead researcher I had already sold everything. At that time there were no more conflicts of interest.

In 2009, the U.S. Senate discovered that Martin Leon had not declared multinational funding of millions of dollars to him and his foundation. But the scandal didn't stop relations with companies. Between 2013 and 2016, Leon went on to receive another $700,000. After selling his company to Edwards, the professor led the TAVI studies in the U.S. to obtain the certifications. These studies were funded by Edwards itself.

Edwards is one of the major funders of Columbia University, where you do your research.

Edwards supports clinical trials at Columbia, just like it does for a hundred other institutions.

In 2015, in Chicago, however, you declared that you had financial and economic relations with the main companies that later produced the TAVI: Edwards, Medtronic, Abbott, Boston...

This interview is becoming a conflict of interest interview.
Professor, conflicts of interest when it comes to medicine and research are inherent to the subject.

MARTIN LEON - COLUMBIA UNIVERSITY MEDICAL CENTER - NEW YORK
You're trying to create a problem where there is none. The interview ends here.

GIULIO VALESINI OFF SCREEN
If the studies presented in America by Edwards, the company that bought the patent for the first TAVI from Leon, are reassuring, those of our authorities are a little less so. We are among the top users in Europe. Studies by the Observant Group, coordinated by the Italian National Institute of Health, show that three years after surgery, the mortality rate of younger patients treated with TAVI is higher than those treated surgically. The French doctor Jean Francois Obadia has analysed the data of all European registries.

JEAN FRANÇOIS OBADIA - CHIEF OF CARDIAC SURGERY, LUIS PRADEL HOSPITAL - LYON
The information we have, though not complete, indicates risks of degeneration of the biological valves after the TAVI procedure.

GIULIO VALESINI
Do we need a longer follow-up before we start implanting TAVI valves in younger patients?

JEAN FRANÇOIS OBADIA - CHIEF OF CARDIAC SURGERY, LUIS PRADEL HOSPITAL - LYON
Absolutely. But the criterion is not age, it's life expectancy. We need to stay calm and wait for the long-term results; only then can we expand the patient base. Otherwise, we could have a catastrophe. Let me give you an example: fifteen years ago there was a surgical valve that looked super promising; but it turned out to be a disaster. But it took us almost ten years to figure that out. And today we're re-operating all the patients.

GIULIO VALESINI OFF SCREEN
But another disturbing detail also emerged from the Italian study: in Italy, between 2011 and 2014, TAVI was also implanted in patients younger than the European average. A use at the time not in line with Community guidelines and defined as potentially worrying. Observant also includes Corrado Tamburino, who ten years ago implanted the first TAVI in Italy. His scrubs are double-faced: he is also a consultant for companies such as Edwards, Medtronic, CeloNova and Abbott.

CORRADO TAMBURINO - DIRECTOR OF FERRAROTTO HOSPITAL - CATANIA
But I have conflicts of relationships, conferences, participation in studies. They call me for example for advisory boards.

GIULIO VALESINI
And do you take money for this, professor?

CORRADO TAMBURINO - DIRECTOR OF FERRAROTTO HOSPITAL - CATANIA
This one yes.

GIULIO VALESINI
How much does being funded by the large companies that produce TAVI valves influence studies?

**CORRADO TAMBURINO - DIRECTOR OF FERRAROTTO HOSPITAL - CATANIA**

Look.

**GIULIO VALESINI**

It's like, isn't it?

**CORRADO TAMBURINO - DIRECTOR OF FERRAROTTO HOSPITAL - CATANIA**

Sure, but it's clear. What you're saying is right. But these studies are better than no studies!

**GIULIO VALESINI**

As soon as I know that members like you in Observant II receive consulting assignments, they get money from companies but they are independent.

**CORRADO TAMBURINO - DIRECTOR OF FERRAROTTO HOSPITAL - CATANIA**

Look, when they call in a lawyer to advise them, do they have to pay for it or not? And why can't a doctor?

**GIULIO VALESINI**

But it's biased. A physician...

**CORRADO TAMBURINO - DIRECTOR OF FERRAROTTO HOSPITAL - CATANIA**

The data over time says whether one's biased or not: if you sponsor a hoax, you can see it.

**GIULIO VALESINI OFF SCREEN**

The problem is that the person who manages the data on the valves is the same person who sells them. The only national registry on patients who have implanted TAVI valves and on any complications belongs to a private company. The multinational Medtronic.

**CORRADO TAMBURINO - DIRECTOR OF FERRAROTTO HOSPITAL - CATANIA**

The data is self-reported, there are no checks.

**GIULIO VALESINI**

Why isn't there a controlled TAVI registry?

**CORRADO TAMBURINO - DIRECTOR OF FERRAROTTO HOSPITAL - CATANIA**

I think it should be sponsored by the Ministry of Health because you have to pay for monitors, it is a study that costs.

**GIULIO VALESINI**

In a conference in 2015 there was talk of a TAVI implants increasing four-fold by 2025. Is that plausible?

**CORRADO TAMBURINO - DIRECTOR OF FERRAROTTO HOSPITAL - CATANIA**

I do think so. Almost all patients above an age group and I'd say 70 years and over will get a TAVI.

**GIULIO VALESINI OFF SCREEN**
Professor Tamburino is so convinced of TAVI's growth that he invested €200,000 euros in Medtronic and Edwards shares. Also the well-known cardiologist Antonio Colombo, a consultant and shareholder of Direct Flow Medical, a Californian start-up that produced another model of TAVI valve, believed in it. Professor Colombo also participated in the studies to obtain the CE mark, necessary to sell it in Europe.

ANTONIO COLOMBO - CHIEF OF INTERVENTIONAL CARDIOLOGY HOSPITAL, SAN RAFFAELE - MILAN
Direct Flow gave me options at the beginning, but they were no good because the company went bust.

GIULIO VALESINI
One wonders: does Professor Colombo, who is both a shareholder and an investigator of the same product, have a clean conscience?

ANTONIO COLOMBO - CHIEF OF INTERVENTIONAL CARDIOLOGY HOSPITAL, SAN RAFFAELE - MILAN
But I wasn't the only one implanting the valves... It was known to everyone.

GIULIO VALESINI
But perhaps someone who is a shareholder should not also be the investigator of his product.

ANTONIO COLOMBO - CHIEF OF INTERVENTIONAL CARDIOLOGY HOSPITAL, SAN RAFFAELE - MILAN
Usually no. I was really a very small shareholder. So...

GIULIO VALESINI
Look, it's just a curiosity: how much can a renowned doctor like you make from a large corporation to be a consultant, to go and talk at conferences...

ANTONIO COLOMBO - CHIEF OF INTERVENTIONAL CARDIOLOGY HOSPITAL, SAN RAFFAELE - MILAN
He could get 300-400 euros per hour.

GIULIO VALESINI OFF SCREEN
Professor Colombo is in business with the Mediolanum Cardio Research, whose members include the controversial German cardiologist Eberhard Grube: he too took part in the studies for the CE mark of the Direct Flow valve.

ANTONIO COLOMBO - CHIEF OF INTERVENTIONAL CARDIOLOGY HOSPITAL, SAN RAFFAELE - MILAN
If you don't have an economic incentive. Awake at night, Sundays...

GIULIO VALESINI
But isn't patient health enough as an incentive?

ANTONIO COLOMBO - CHIEF OF INTERVENTIONAL CARDIOLOGY HOSPITAL, SAN RAFFAELE - MILAN
I mean, we know. Homo homini lupus. You need other things. But it is right to keep an eye on whether the economic incentive serves as a motivation to work more or as a motivation to do other things. But we see right away. There are some who push...
GIULIO VALESINI
Look, but there was that colleague of yours, Eberhard Grube.

ANTONIO COLOMBO - CHIEF OF INTERVENTIONAL CARDIOLOGY HOSPITAL, SAN RAFFAELE - MILAN
But he's got loads of conflicts of interest.

GIULIO VALESINI
But you were his partner, right?

ANTONIO COLOMBO - CHIEF OF INTERVENTIONAL CARDIOLOGY HOSPITAL, SAN RAFFAELE - MILAN
He wasn't my partner, let's do some..

GIULIO VALESINI
At Mediolanum Research..

ANTONIO COLOMBO - CHIEF OF INTERVENTIONAL CARDIOLOGY HOSPITAL, SAN RAFFAELE - MILAN
Yeah, but he's out now. He was there a short time. But he's... he's well-placed.

GIULIO VALESINI
I says too much...

ANTONIO COLOMBO - CHIEF OF INTERVENTIONAL CARDIOLOGY HOSPITAL, SAN RAFFAELE - MILAN
Too much. But he's known that when he says something, we now know it.

GIULIO VALESINI
He says so because he's got...

ANTONIO COLOMBO - CHIEF OF INTERVENTIONAL CARDIOLOGY HOSPITAL, SAN RAFFAELE - MILAN
Of course. We don't take his words seriously.

GIULIO VALESINI OFF SCREEN
Yet Professor Eberhard Grube is considered a guru by multinationals that produce stents. He's even got a finger in several pies. He was a shareholder and consultant of Corvalve, the company that designed one of the first TAVI valves, which then passed into the hands of Medtronic for $700 million.

EBERHARD GRUBE - DIRECTOR OF THE CARDIOLOGY INNOVATION CENTRE - HERZZENTRUM BONN
Companies look for market opportunities. Of course. Now the problem is to go to markets in developing countries, to Latin America and Asia, where the issue of refunds is very critical. I'm sure that as soon as patients and hospitals don't have to pay for TAVI themselves, the procedure will hit it big.

GIULIO VALESINI
What is your relationship with Medtronic? Financial relations, for example.

EBERHARD GRUBE - DIRECTOR OF THE CARDIOLOGY INNOVATION CENTRE - HERZZENTRUM BONN
No, no, no, no. I was one of the developers of the valve; then Medtronic bought Corevalve. But once the transaction was done, there was no more conflict, because everything was paid to me before.

GIULIO VALESINI
But it is a little risky in the eyes of public opinion to say: "Dr. Grube, when he does an assessment and has a relationship with the company, has a clean conscience or has business interests that lead him to have opinions..."

EBERHARD GRUBE - DIRECTOR OF THE CARDIOLOGY INNOVATION CENTRE - HERZZENTRUM BONN
But it has nothing to do with investments anymore!

GIULIO VALESINI OFF SCREEN
Grube had another passion: heart stents. He tested them for Biosensors, a Singapore-based company. In exchange, he received 200 thousand stock options, worth around one million euros. He never declared the conflict, but it came to the surface from the secret archives of the Paradise Papers.

GIULIO VALESINI
You've promoted Biosensors stents a lot.

EBERHARD GRUBE - DIRECTOR OF THE CARDIOLOGY INNOVATION CENTRE - HERZZENTRUM BONN
Yes, I still do

GIULIO VALESINI
You had 200,000 Biosensor stock options.

EBERHARD GRUBE - DIRECTOR OF THE CARDIOLOGY INNOVATION CENTRE - HERZZENTRUM BONN
What are you looking for now? Are we talking about financial interests and stock options? Or what? I don't understand why I'm talking about my stock options in front of a camera.

GIULIO VALESINI
But did you or didn’t you have Biosensors stock options?

EBERHARD GRUBE - DIRECTOR OF THE CARDIOLOGY INNOVATION CENTRE - HERZZENTRUM BONN
That's enough!

GIULIO VALESINI
Finish?

EBERHARD GRUBE - DIRECTOR OF THE CARDIOLOGY INNOVATION CENTRE - HERZZENTRUM BONN
You’re speaking to me about TAVI.

GIULIO VALESINI
Stents. No, no.
EBERHARD GRUBE - DIRECTOR OF THE CARDIOLOGY INNOVATION CENTRE - HERZZENTRUM BONN

Do you want to talk about stock options and conflicts of interest? My friend, go to your Italian colleagues, not me.

SIGFRIDO RANUCCI IN THE STUDIO

Boy, how angry Professor Grube got when we reminded him of his stock options in tax havens. He had bright eyes, however, when he imagined conquering new markets covered by the national health system. The system is so broken in that it is replicating itself, cloning itself. A physician helps a start-up, invents a product, patents it and then sells it to a multinational company: the physician as a shareholder reaps the money, then continues to do studies, fuelled, subsidised by a multinational, to develop and promote the product. These studies are then published in prestigious journals and presented at conferences. It takes an incentive to stay awake, says Professor Colombo instead. And that's OK, because they do a commendable job, they save lives. It is a little less commendable, however, when he speaks of "homo homini lupus," it can't be reconciled with the Hippocratic oath, where a doctor swears on his freedom and independence and swears to oppose any attempt at be conditioned which may ever occur. "You're right," says Professor Tamburino, when you talk about studies funded by multinationals, but it's better to have that money than nothing. And that's OK, because good doctors are also trained. Multinationals finance hospitals, finance universities, finance clinical trials, finance those doctors who teach other doctors how to implant the product they sell. Basically, the system drives itself. In the United States, last year, eight billion euros went out from multinationals to doctors and research foundations. We can know that because there is an obligation of transparency there. Not here, no. But perhaps you should know whether a medical device is actually the best solution for you when a doctor offers you one as the best choice or whether he does so because he has hidden shares in tax havens. That too, you know. The embrace between multinationals and doctors is a tight one.

MARCO BOBBIO - CARDIOLOGIST AND WRITER

If you become a good clinician, you will have the support of and be supported by companies, but in turn companies make you a leading person because they propose you at conferences, seminars, round tables and so on.

GIULIO VALESINI

Did they use to invite you?

MARCO BOBBIO - CARDIOLOGIST AND WRITER

I was part of a fairly large circle of so-called opinion leaders, then at some point I realized that somehow my judgment was influenced by these invitations and then I decided to stop and I drifted a bit, but I did my job with absolute serenity.

GIULIO VALESINI

I've got a clean conscience because I know that the doctor who orders or implants a device, implants the device because it was the best thing for me; there is a filter.

MARCO BOBBIO - CARDIOLOGIST AND WRITER

Almost all doctors are convinced to choose the best device because they do not realize, in many cases, that they are economically influenced by companies, but it is not just an economic matter, but it also has to do with their career if they choose one device over another.
Tor Vergata General Hospital is one of the largest hospitals in Italy. Here, in 2012, Medtronic financed a research project for the cardiology unit with €34,000.

Good morning, Professor. I'm Giulio Valesini from Rai.

The Chief Francesco Romeo decided to use it to hire a professional specialized in TAVI.

Up to what age can you place TAVI valves? Because I see it's going down a little now. Moderate risk, slightly younger patients...

Today, in America intermediate risk has been cleared, as well as low risk. They'd put it in everyone in America today.

Would you put a TAVI in a patient like me?

I'd put a TAVI in today.

Me? I'm 43.

43 years old? Okay, well, we're making a case out of it.

How many do you do a year?

We do a hundred.

What is the best brand, Professor? Can I ask you that?

Look, we use Medtronic a lot.

But has Medtronic ever given money to your hospital?

To my hospital? No, absolutely not.
GIULIO VALESINI
Are you sure?

FRANCESCO ROMEO - CHIEF OF CARDIOLOGY AT TOR VERGATA GENERAL HOSPITAL
Absolutely. The shameful thing is that they sell them to private facilities for €6 thousand, to public facilities for €20 thousand. That's the shame! Do you know how I treat them? Like cheap door-to-door salesmen. If we have coffee, it's always on me.

GIULIO VALESINI
All the doctors say: "If you're good, sooner or later there'll be a conflict of interest."

FRANCESCO ROMEO - CHIEF OF CARDIOLOGY AT TOR VERGATA GENERAL HOSPITAL
But it's not true. They're just a bunch of beggars who need money. I don't need money.

GIULIO VALESINI OFF SCREEN
And if it is the outgoing president of the Italian Society of Cardiology who says so, you need to take him serious. The scholarship paid by Medtronic went to Gianpaolo Ussia, the only candidate in the competition. With an outstanding CV, Ussia has been a consultant since 2008 for a number of companies, including Medtronic. He’s a proctor: he teaches how to implant the heart valves of the American multinational. For years in Tor Vergata, mainly Medtronic's TAVI devices have been implanted.

GIAN PAOLO USSIA - TOR VERGATA UNIVERSITY OF ROME
I am a proctor for several companies, but this is something that has never influenced my work.

GIULIO VALESINI
In the name of transparency, can I ask you how much you are being paid by the companies?

GIAN PAOLO USSIA - TOR VERGATA UNIVERSITY OF ROME
Each procedure costs about a thousand euros.

GIULIO VALESINI
For every procedure?

GIAN PAOLO USSIA - TOR VERGATA UNIVERSITY OF ROME
No, no, a day.

GIULIO VALESINI
In 2012 you went to Tor Vergata with a contract sponsored by Medtronic, in 2012? As a proctor? As a consultant?

GIAN PAOLO USSIA - TOR VERGATA UNIVERSITY OF ROME
No, no.

GIULIO VALESINI
Are you sure?
GIAN PAOLO USSIA - TOR VERGATA UNIVERSITY OF ROME
Sure.

GIULIO VALESINI
May I ask you one last thing? For transparency.

GIAN PAOLO USSIA - TOR VERGATA UNIVERSITY OF ROME
Listen, when they gave me the contract, it's not that I asked why are you giving me the contract.

GIULIO VALESINI
Why not? They give you a contract and you don't know why they give you a contract!

GIAN PAOLO USSIA - TOR VERGATA UNIVERSITY OF ROME
Goodbye!

GIULIO VALESINI OFF SCREEN
Medtronic's donation to the cardiology department headed by Professor Romeo is very important to the chief physician. We meet him again at a conference.

FRANCESCO ROMEO - CHIEF OF CARDIOLOGY AT TOR VERGATA GENERAL HOSPITAL
But why were you asking me those questions yesterday? I photographed you yesterday, and I sent your picture around and I got information about you.

GIULIO VALESINI
I hope it's good.

FRANCESCO ROMEO - CHIEF OF CARDIOLOGY AT TOR VERGATA GENERAL HOSPITAL
Yes, but you can't ask those questions: "Is it true that you have received funding from companies?"

GIULIO VALESINI
But you said no.

FRANCESCO ROMEO - CHIEF OF CARDIOLOGY AT TOR VERGATA GENERAL HOSPITAL
But do you realize what you're implying?

GIULIO VALESINI
No, but.

FRANCESCO ROMEO - CHIEF OF CARDIOLOGY AT TOR VERGATA GENERAL HOSPITAL
I know the director, the deputy director, all the editors at Rai 3: serious people, they're friends of mine. I was with a colleague of mine and I told him: "When I talk to someone, you have to photograph me," because it was a piece of advice given to me by my relatives. The ones who work for Digos [the Italian Political Squad]. Because someday someone might say "I was talking to..."

GIULIO VALESINI
Digos will tell you good things about me. Don't worry.
Before proceeding with a TAVI implant, international guidelines require hospitals to set up a team of experts: the heart team. A cardiologist, cardiac surgeon, anaesthetist and other specialists must work together to determine the best care for a patient. This is also recommended by the Lazio Region, which pays for the valves.

The heart team is mandatory in every hospital where a TAVI is implanted.

What are the risks if there weren't a heart team to decide?

One technique could be preferred over another. In many cases there is a preference for TAVI because of industry pressure, and the fact that if you ask patients: "Do you want me to open your chest or cut you over the leg?" They always choose TAVI.

And even the industry, since a TAVI valve costs about 20 thousand euros and a surgical one 3 thousand. At Tor Vergata, they didn’t have a heart team for a long time. Professor Ruvolo, chief of cardiac surgery, asked the general management to set it up a year ago. But no one replied. It was suddenly appointed a few weeks ago: and by coincidence, only after Report’s request for an interview.

But what does that mean?

You mean there were inappropriate instructions?

No, I'm not saying it's mandatory to have a Heart team

And we’ve got it!

It was set up in October.

All the patients. But look that this is something. Don't go... You're saying nonsense.
As usual.

FRANCESCO ROMEO - CHIEF CARDIOLOGIST AT TOR VERGATA GENERAL HOSPITAL
More nonsense.

SIGFRIDO RANUCCI IN THE STUDIO
We hope that we have not said any because the issue is particularly serious. Instead, he said a certified piece of nonsense when he said he knew our talented director of Rai 3, Stefano Coletta. It's not true. While, instead, we agree with him when he says that it is a shame that a TAVI is offered by the multinational to the national health system twice as much as it is offered to private clinics. It is a shame to milk the dried breast of the national health system. In recent days there was a strike of doctors and nurses. It's the other side of the coin in our story, that of the multinationals with billionaire turnovers, and of the doctors with shares in the Cayman Islands. There are, on this other side, doctors without a contract, underpaid nurses who are forced to work heavy shifts, and cuts in emergency departments. Is this the healthcare we want? Returning to our professor Romeo and the TAVI valves, he says he has implanted them according to the guidelines, which, however, as we point out, provide for setting up a heart team, which Tor Vergata did not have until we raised the issue. Romeo said: I've implanted them, according to the guidelines, in 80-year-old patients. And we believe him, until proven otherwise, but he had shown a certain ease in wanting to implant one in our Giulio Valesini, forty-three years old, who, thank God, is in excellent health. But Professor Romeo has also implanted the pacemaker, the new St. Jude pacemaker. Behind St. Jude, there are always investment funds that are in a hurry to get to the market first. St. Jude's new pacemaker had one advantage: it was tiny, wireless. And it was so small, the Nanostim, as to have a commercial claiming: "So small, that it stays in your heart." Unfortunately, they were right. Never has advertising been so true to the point.

GIULIO VALESINI OFF SCREEN
In 2014, at Tor Vergata General Hospital, Professor Romeo implanted a Nanostim, the innovative pacemaker by St Jude Medical. He was the first in Lazio to perform the procedure. Together with him, in the team, there was the cardiologist Domenico Sergi, his nephew, who in 2013 was the only candidate and won a five-year scholarship sponsored at the university by St. Jude Medical.

FRANCESCO ROMEO - CHIEF OF CARDIOLOGY AT TOR VERGATA GENERAL HOSPITAL
What is the Nanostim? You tell me.

GIULIO VALESINI
You were the first in Lazio to perform the procedure, right?

FRANCESCO ROMEO - CHIEF OF CARDIOLOGY AT TOR VERGATA GENERAL HOSPITAL
And... You tell me what the Nanostim is.

GIULIO VALESINI
You tell me, you're the doctor.

FRANCESCO ROMEO - CHIEF OF CARDIOLOGY AT TOR VERGATA GENERAL HOSPITAL
OK, so I don’t remember what it is.

GIULIO VALESINI
Are you kidding?

FRANCESCO ROMEO - CHIEF OF CARDIOLOGY AT TOR VERGATA GENERAL HOSPITAL
No, I'm not kidding.

GIULIO VALESINI
I'm asking you what do you think about that product.

FRANCESCO ROMEO - CHIEF OF CARDIOLOGY AT TOR VERGATA GENERAL HOSPITAL
I hope it's all that way. It's the future.

GIULIO VALESINI OFF SCREEN
Small and lightweight, the Nanostim is the first wireless pacemaker to reach the market. The size of a one-euro coin. Quickly implantable and easy to remove. The battery is guaranteed for more than 10 years: or at least, that's what the patient information sheet says. A major step forward compared to traditional pacemakers.

CLAUDIO TONDO - COORDINATOR OF ARRHYTHMOLOGY AT MONZINO HOSPITAL - MILAN
One of the advantages is that the risk of infection is substantially zero. If you want, there is also an aesthetic problem that should not be underestimated.

GIULIO VALESINI
The scar.

CLAUDIO TONDO - COORDINATOR OF ARRHYTHMOLOGY AT MONZINO HOSPITAL - MILAN
That comes into play in the decision.

GIULIO VALESINI OFF SCREEN
The wireless pacemaker is an idea of the start-up Nanostim Inc. which tested it on a dozen sheep in the Czech Republic. In 2013 St. Jude put its eyes on the patent and promised to acquire the company for $123 million. At one condition: that it first obtain the CE mark necessary for its sale on the European market. Certification came after a clinical trial conducted in record time: three months and 36 patients. The first signature on the trial was Dr. Vivek Reddy’s. He too wearing two suits: that of doctor and shareholder of Nanostim Inc.

CARLO PAPPONE - CHIEF OF ARRHYTHMOLOGY AT SAN DONATO GENERAL HOSPITAL
The trial was carried out according to the rules that the ethics committees and European and international rules set out.

GIULIO VALESINI
But, in your opinion, three months and 33 patients in the Leadless study for CE marking approval. Were they too few? Were they sufficient before placing it on the market and implanting it in patients?
CARLO PAPPONE - CHIEF OF ARRHYTHMOLOGY AT SAN DONATO GENERAL HOSPITAL

They were few to me. The world of devices is a very important business because it generates wealth. It is good that research is financed with the money of multinationals.

GIULIO VALESINI

Isn't there a conflict of interest, professor, in the sale of that device?

CARLO PAPPONE - CHIEF OF ARRHYTHMOLOGY AT SAN DONATO GENERAL HOSPITAL

The sponsorship is declared.

GIULIO VALESINI

Is that all it takes?

CARLO PAPPONE - CHIEF OF ARRHYTHMOLOGY AT SAN DONATO GENERAL HOSPITAL

Ethics committees are aware of this, hospitals are aware of this.

GIULIO VALESINI OFF SCREEN

Once certified, St. Jude sponsored a European trial. Italy was one of the leading countries with six hospitals in Lombardy. But then came the problems. In 2014, a few months after the start of sales in Europe, the multinational sent out a warning: there’s a risk of cardiac perforation. The implantation point needs to be changed.

GIULIO VALESINI

You were the first in Italy to implant St. Jude's leadless device. You participated in that trial.

CARLO PAPPONE - CHIEF OF ARRHYTHMOLOGY AT SAN DONATO GENERAL HOSPITAL

I participated in that trial.

GIULIO VALESINI

What do you think?

CARLO PAPPONE - CHIEF OF ARRHYTHMOLOGY AT SAN DONATO GENERAL HOSPITAL

I've implanted four of these devices.

GIULIO VALESINI

How are the batteries?

CARLO PAPPONE - CHIEF OF ARRHYTHMOLOGY AT SAN DONATO GENERAL HOSPITAL

The battery, which had been declared to last even ten years, lasted very little.

GIULIO VALESINI OFF SCREEN

In October 2016, St. Jude called on doctors to suspend implants. They realized that the batteries, guaranteed for ten years, would suddenly go dead, putting the patient's life at risk.
CLAUDIO TONDO - COORDINATOR OF ARRHYTHMOLOGY AT MONZINO HOSPITAL - MILAN
The medical electrical industry that supplied the system was not the manufacturer itself, but they are batteries that are...

GIULIO VALESINI
Assembled.

CLAUDIO TONDO - COORDINATOR OF ARRHYTHMOLOGY AT MONZINO HOSPITAL - MILAN
Assembled and given to different manufacturers. What happened...

GIULIO VALESINI
Is that they suddenly went dead.

CLAUDIO TONDO - COORDINATOR OF ARRHYTHMOLOGY AT MONZINO HOSPITAL - MILAN
It's a clear that there was a leak of electrolytes, so there was a leak of liquid. That did not allow..

GIULIO VALESINI
That reduced the battery’s capacity...

CLAUDIO TONDO - COORDINATOR OF ARRHYTHMOLOGY AT MONZINO HOSPITAL - MILAN
It resulted in an extremely rapid reduction in charge. That's the problem.

GIULIO VALESINI
Because the battery leaked?

CLAUDIO TONDO - COORDINATOR OF ARRHYTHMOLOGY AT MONZINO HOSPITAL - MILAN
That’s right. However, in this case it was objectively impossible to predict a battery default.

GIULIO VALESINI OFF SCREEN
But the multinational was no stranger to such problems. Also in 2016 it was forced to recall some defibrillators, once again due to a battery problem, produced by their official supplier. But this FDA document shows that the multinational already knew in 2011 of the defects in its defibrillators. And soon it had to deal with another problem: in 2017, Saint Jude, which in the meantime was taken over by Abbott, discovered that the Nanostim docking button came off

GIULIO VALESINI
In January 2017, there was the detachment of the buttons to retract the leadless. You’re laughing. Is that correct?

CARLO PAPPONE - CHIEF OF ARRHYTHMOLOGY AT SAN DONATO GENERAL HOSPITAL
Right.

GIULIO VALESINI
So that's three.

**CARLO PAPPONE - CHIEF OF ARRHYTHMOLOGY AT SAN DONATO GENERAL HOSPITAL**
But this is also part of the experience that comes from research.

**GIULIO VALESINI**
What about the patient?

**CARLO PAPPONE - CHIEF OF ARRHYTHMOLOGY AT SAN DONATO GENERAL HOSPITAL**
The patient is informed.

**GIULIO VALESINI OFF SCREEN**
This document, until now secret, shows the adverse events. There are also Italian cases: the pacemaker was not fixed well in the heart of a patient, it came off and ended up elsewhere during implantation. Then a case of pericardial effusion, one of cardiac perforation. Several patients had to have the device replaced. In Germany, there were also two deaths related to the pacemaker procedure. In the United States, Nanostim never passed the trial phase: St. Jude has invited doctors to monitor all patients involved in Europe.

**GIULIO VALESINI**
What did you do? Did you replace it or did you implant another one?

**CARLO PAPPONE - CHIEF OF ARRHYTHMOLOGY AT SAN DONATO GENERAL HOSPITAL**
I implanted a conventional pacemaker.

**GIULIO VALESINI**
But did you leave the other one in?

**CARLO PAPPONE - CHIEF OF ARRHYTHMOLOGY AT SAN DONATO GENERAL HOSPITAL**
A decision was made to leave it in and put a normal one in. Look, but history is full of devices that only show signs of malfunction after many years.

**GIULIO VALESINI OFF SCREEN**
The solution of leaving the old tool in the hearts of patients was also chosen in other hospitals. Is it possible that a device with so many defects arrived on the market? Who was supposed to check the scientific documentation for the necessary authorizations? The CE mark is obtained with the OK of a notified body. The first one that Nanostim contacted was the German body TÜV, who was not very convinced and asked for further trials. At that point, the start-up decided to change its controller and turned to the British BSI that granted authorisation without objecting.

**CARL HENEGHAN - CENTRE FOR EVIDENCE-BASED MEDICINE - UNIVERSITY OF OXFORD**
But it is the industry itself that decides whether the scientific evidence supporting a product is sufficient. All companies know that here in Europe you pay to hear them tell you whatever you want. And if you don't like the answer of one body, you can go to the other: it's like shopping.
To be marketed, a drug must demonstrate its efficacy in a randomised trial over a number of years. For devices this unfortunately does not exist; therefore, devices are put on the market that you do not know if they will work well, if they will give benefits to patients and especially if they will have advantages over previous devices.

How do you explain that sometimes devices that fail the real-life test reach the market? They fail in the sense that they’re not safe.

Well, because the moment I have an idea and produce a new device, I know that the other companies will be coming soon too, so I have to enter the market before they do.

We asked Abbott, which owns St. Jude and Nanostim, for information, but they preferred not to answer us. I guess that they are not interested in Italian citizens, as a public to be informed. They are only interested in patients where to implant their devices and the health care system. Because it’s the payer. But this is a typical example of when haste makes waste: because the Nanostim has ended up in a drawer and who knows whether it'll ever be pulled out again. It has been replaced by a pacemaker with similar characteristics, the rival Medtronic, because it entered the market, with two years, after two years of rigorous clinical trials. But did a defective device reach the market? It's the system that’s full of holes. The Government chose to give up to its role as controller. It entrusted the task to about fifty private bodies, known as "notified" bodies, because they issue the certificate of the European Community, the CE certificate that allows you to sell a product throughout the market. The only problem is that, instead of being controllers, there is the risk that they become business partners of those who want to enter the market first, because these multinationals pay them. Until 2017 the system did not provide the benefit of showing the clinical benefit. And so even hip replacements or insulin delivery devices did not work well. The FDA, the US government agency that controls medical devices, and they too have missed something, chastised us, with a critical article. It said: Europe approved devices that would never have passed in the US. And, in addition, they noted the fact that citizens—and this is important—in America can inquire about the clinical trials that have led to the approval of a device. Not here, no. This is because the data, the clinical trial, are considered an intellectual property. It's so intellectual that we have risked approving, certifying a net for oranges as a medical device.

In the United States, devices are authorised to enter the market by the FDA, a federal agency funded with public and private money. A few years ago, the director of the FDA's Center for Devices, Jeff Shuren, said, talking about some medical devices withdrawn from the European market and rejected by the FDA: "In the United States, we don't use people as guinea pigs."

That's your opinion, there's no evidence.

An authoritative opinion, though.
RONALD BOUMANS - SENIOR GLOBAL REGULATORY CONSULTANT - EMERGO
I think that European patients are not guinea pigs and have never been guinea pigs. They benefited from an innovative market and new devices well ahead of American patients. There have been many incidents in United States, too; so I don't see much difference.

GIULIO VALESINI OFF SCREEN
A medical device is approved in Europe about three years before the United States. Alan Fraser is a big shot in the European Society of Cardiology. And he's in charge of European rules. A few weeks ago he publicly stated that the first approved devices in Europe have twice as many recalls as those are passed before in the United States. According to a study on 309 cardiovascular, neurological and orthopaedic devices published by the British Medical Journal, 27 versus 14 percent.

GIULIO VALESINI
Am I making it too simple when I say that, based on these figures, we, in Europe, have made a sort of trade-off: speed in exchange for safety?

ENRICO CAIANI - COMMITTEE FOR REGULATORY AFFAIRS - EUROPEAN SOCIETY OF CARDIOLOGY
Looking at how the system was designed, probably yes. I always see safety as being linked to transparency for the end user or for those who have to make a decision.

GIULIO VALESINI OFF SCREEN
The manufacturer can choose which notified body to contact to have its device certified. And there is no obligation to make the documentation public.

ENRICO CAIANI - COMMITTEE FOR REGULATORY AFFAIRS - EUROPEAN SOCIETY OF CARDIOLOGY
Basically, the data exist, but are not accessible to the public.

GIULIO VALESINI
So we don't know, as citizens, as patients, as journalists.

ENRICO CAIANI - COMMITTEE FOR REGULATORY AFFAIRS - EUROPEAN SOCIETY OF CARDIOLOGY
There is no obligation of transparency, which is enshrined, instead, for everything public.

GIULIO VALESINI OFF SCREEN
The European Commission knew that the system based on notified bodies did not protect the health of citizens. In a document from 2017, they put it in black and white: some devices were certified even if they were not conforming. But for years they decided not to intervene. The new regulation on medical devices will take effect in 2020. However, there will be no transition to a centralised public control body, which would have cost just €12 million a year. The notified bodies stay where they are, to the delight of medical companies, always advised by an Italian: Dario Pirovano. The grey eminence of the sector: twenty years ago he helped Europe write the rules; today he is now on the other side of the barricade.

GIULIO VALESINI
Why are you so opposed to a radical change to an FDA-like model, i.e., to keep to the notified bodies.
DARIO PIROVANO - CONSULTANT OF THE EUROPEAN ASSOCIATION OF MEDTECH COMPANIES
Because it makes no sense in Europe.

GIULIO VALESINI
Why?

DARIO PIROVANO - CONSULTANT OF THE EUROPEAN ASSOCIATION OF MEDTECH COMPANIES
But I'm here. We were supposed to be here six months. I'm a bioengineer. I've been working on medical devices for 40 years: I can assure you that it wouldn't work out here.

GIULIO VALESINI
Why?

DARIO PIROVANO - CONSULTANT OF THE EUROPEAN ASSOCIATION OF MEDTECH COMPANIES
Because there are 27 Member States, not one.

GIULIO VALESINI
Yes, but the data, look, one thing for public health.

DARIO PIROVANO - CONSULTANT OF THE EUROPEAN ASSOCIATION OF MEDTECH COMPANIES
No, no, no, no.

GIULIO VALESINI
No, there's only one thing that struck me about these data.

DARIO PIROVANO - CONSULTANT OF THE EUROPEAN ASSOCIATION OF MEDTECH COMPANIES
Except they made a mess... even at the FDA so you can't see it, because you should.

GIULIO VALESINI
Look at this, look at this, yes everyone was wrong, but look at this: a device approved first in Europe, has twice as many recalls and adverse events than those in the United States and has three times.

DARIO PIROVANO - CONSULTANT OF THE EUROPEAN ASSOCIATION OF MEDTECH COMPANIES
We can show you exactly the opposite.

GIULIO VALESINI
A five-year series.

DARIO PIROVANO - CONSULTANT OF THE EUROPEAN ASSOCIATION OF MEDTECH COMPANIES
No, no. We can show you exactly the opposite, on another product it is exactly the opposite.

GIULIO VALESINI
But a centralised public body would avoid the conflict of interest of notified bodies and companies; I pay my controller.

DARIO PIROVANO - CONSULTANT OF THE EUROPEAN ASSOCIATION OF MEDTECH COMPANIES
No.

GIULIO VALESINI
And why not?

DARIO PIROVANO - CONSULTANT OF THE EUROPEAN ASSOCIATION OF MEDTECH COMPANIES
No, you don't pay any controller.

GIULIO VALESINI
What do you mean no? I choose my controller, I pay him, why not?

DARIO PIROVANO - CONSULTANT OF THE EUROPEAN ASSOCIATION OF MEDTECH COMPANIES
This is an old tale they've been trying to sell for 40 years; it’s not true.

GIULIO VALESINI
That's the way it is.

DARIO PIROVANO - CONSULTANT OF THE EUROPEAN ASSOCIATION OF MEDTECH COMPANIES
Not at all!

GIULIO VALESINI
I choose the notified body, I pay it.

DARIO PIROVANO - CONSULTANT OF THE EUROPEAN ASSOCIATION OF MEDTECH COMPANIES
Yes, but the notified body will kick your ass if you're not..

GIULIO VALESINI
Well, all the scandals that have happened show that every now and then some EC mark has passed.

DARIO PIROVANO - CONSULTANT OF THE EUROPEAN ASSOCIATION OF MEDTECH COMPANIES
But not at all; scandals are frauds.

GIULIO VALESINI
I get it, but someone passed them through Dr. Pirovano.

DARIO PIROVANO - CONSULTANT OF THE EUROPEAN ASSOCIATION OF MEDTECH COMPANIES
No, no one passes frauds.

GIULIO VALESINI OFF SCREEN
Dr Pirovano is by nature an optimist. Perhaps he does not know that even a net containing oranges, thanks to current mechanisms, can be passed off as a medical
device to be implanted in the body of women to treat problems of incontinence and prolapse after childbirth. It is even that those who have to certify and grant the CE mark for placing devices on the market are giving a positive assessment of the idea. The story documented by Jet Schouten, a brilliant colleague of the Dutch TV Avodros, partner of the International Consortium of Investigative Journalists, is incredible.

**Jet Schouten - Journalist**
The structure is similar, it's just plastic after all. So we said: "Okay, we need pictures of our device, why don't we go to the supermarket and buy a bag of tangerines?" And we used it.

**Cataldo Ciccolella**
You used the equivalence system to get the mark; what is equivalence?

**Jet Schouten - Journalist**
It's the most popular system if you want to sell a device. You say: this is my device. I don't have to do any clinical trials because there are already equivalent devices on the market; just copy their clinical data and say: "Hey, mine's equivalent."

**Cataldo Ciccolella**
You produced technical and scientific documentation of 121 pages; what did you put in it?

**Jet Schouten - Journalist**
We prepared the clinical data, even exaggerating a bit, to see if the notified bodies would really read the technical literature. We wrote: "One in three women will have permanent injuries if she is implanted with our net." We never thought they'd approve it.

**Giulio Valesini Off Screen**
Yet the notified bodies should have kept their eyes open, because the previously approved nets had caused serious damage in the UK: one in eight patients experienced injuries, infections, and walking issues. However, although Jet Schouten exaggerated the risks, the three notified bodies had nothing to object to the incredible proposal.

**Notified Body 1**
Of course, this doesn't sound like the kind of product you say no to!

**Notified Body 2**
To date, all those who have applied for the CE mark have obtained it.

**Notified Body 1**
In recent years, I've only had to say no to one customer and we follow about 250!

**Jet Schouten - Journalist**
We paid them to evaluate our technical dossier: we wanted them to really understand how ridiculous it was!

**Cataldo Ciccolella**
Are you the one who cheated the system or is it the system that helped you cheat it?

**Jet Schouten - Journalist**
It is very strange for the system to act in this way; the notified bodies treated us as business partners. We asked: "What are the chances of getting the mark if we go with you? And in all three cases, they told us: "Well, the odds are 99 to 100 percent."

GIULIO VALESI

GIULIO VALESINI OFF SCREEN

Italy has also had its own scandals: In recent years almost 4 thousand patients have been forced to be re-operated due to toxic hip replacements produced by Depuy. According to a 2016 study, 68 percent of insulin pumps, implanted in adults and diabetic children, do not work properly and 12 percent do not work at all. To give citizens more transparency, Europe has created Eudamed, a database of all devices. Ronald Boumans is the consultant who worked for the companies on the project.

GIULIO VALESINI

What do you think should be contained in Eudamed that is searchable, visible to the public?

RONALD BOUMANS - SENIOR GLOBAL REGULATORY CONSULTANT - EMERGO

Incident reports will not be published to prevent other companies from misusing them to compete unfairly and to prevent people who are unable to read the data well from being conditioned by them. Patients in the United States often sue for huge amounts of money.

SIGFRIDO RANUCCI IN THE STUDIO

There will be a database. There will be no transparency. That's it, they keep protecting the multinationals. After that, the certification system will remain basically that. The inspirer, the grey eminence, we have seen, is an Italian and, when our Giulio told him: "But is there a risk of fraud?" He says, "No, don't worry, even if the notified bodies are private, if they discover a fraud they..." Then, in reality, even the orange net risked being certified. Then, there were also certifications on devices that proved to be defective. The Italian National Institute of Health also had a laboratory of its own, a notified body, but it has issued certificates that the Rome Public Prosecutor's Office has judged false. False because those tests it certified were never done. We discovered this story in 2015. They accused us of having said something false, they were certified for stents, pacemakers and other devices. Today, they are on trial for having said something false. Now, then, the issue of device incident reports is a serious one. A doctor has to draw up a detailed report on what is happening in the operating room or what is happening around a medical device. But he doesn't always do it. The reports are underestimated, as the Ministry of Health says. They wrote us a letter: unfortunately, "the phenomenon of under-reporting is widespread throughout Europe." The Italian Ministry of Health also explains other detailed things. We are publishing the letter on the website. As we publish it on our site, and here I am proud to inform you, for the first time in history there is a database that covers the safety warnings of medical devices and it regards recalls. It is available to you, to all citizens, to citizens from all over the world. This contribution was made with the help of the journalists of the International Consortium of Investigative Journalism, which Rai, through Report, makes available to you. However, of course, always consult a doctor, because the matter is delicate. And now... 5G.