

SKIN & BONE

The Shadowy
Trade in
Human Body
Parts



THE INTERNATIONAL CONSORTIUM
OF INVESTIGATIVE JOURNALISTS



THE CENTER FOR
PUBLIC INTEGRITY

PRODUCTS MADE FROM HUMAN TISSUE

Dental implants



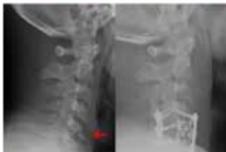
Cruciate ligament reconstruction



Breast reconstruction after cancer



Orthopedic or spinal surgery



Penis enlargement



Bone grafts



Smoothing out wrinkles



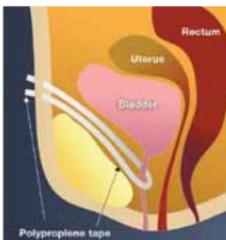
Covering for diabetic foot ulcers



Heart valve replacements



Bladder slings for incontinence



Cornea transplants



Covering for severe burns



Nose reconstruction



HOW SAFE IS HUMAN TISSUE? BY THE NUMBERS.

61,000

allografts

recalled by the FDA between
1994-2007

1,352

reports of adverse events

received by the FDA between
2002-May 2012

40%

of registered tissue banks

have no record of FDA inspection

7%

of foreign tissue banks

have no record of FDA inspection

40

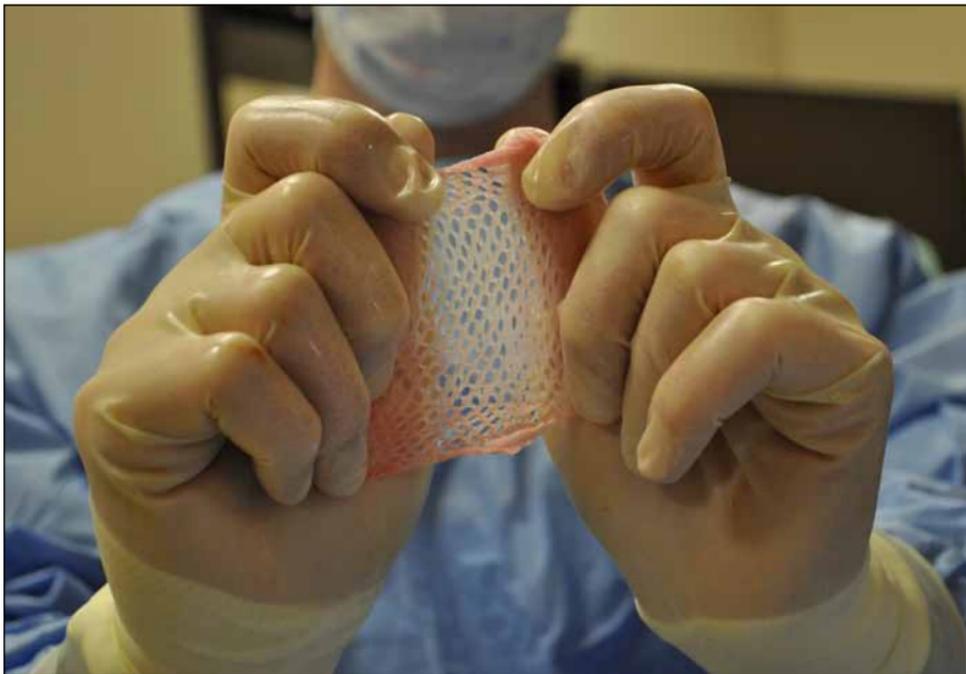
deaths

involving transplanted human tissue
reported between 2002-May 2012

758

complaints

received by RTI Biologics between
Sept. 2010 and Oct. 2011. The
company reported 4 to the FDA.



When skin is meshed, it doubles its size and surface area as a surgical covering. The holes also help with evacuation of liquids during healing.

Photo: Mar Cabra

that are also FDA-registered tissue banks and shipped to Tutogen, a subsidiary of RTI since early 2008.

The first case, from 2005, was dropped when investigators ruled that the law made it difficult to prove whether a crime had been committed. The second case, from 2008, was closed when the supplier on trial died just before a jury re-

turned its verdict. The third and fourth cases, from earlier this year, are still pending.

“If we had any intelligence about a concern, we would flag them accordingly and take the appropriate action,” a high-ranking FDA import official said. “If something came in we’d probably hear about it. But it doesn’t ring a bell with me.”

Hallo,

I joined a team of ICIJ in 2012. ICIJ – that's the International Consortium of investigative journalists. It is a small Washington based NGO but I think you all know ICIJ since its publications about tax paradises all over the world. This is a very large cross border investigation, publications started two years ago and the project is still evolving. The latest coup was Lux-Leaks a few weeks ago.

As a non-profit organization the ICIJ gives its work away for free and relies mostly on donations from foundations and on financial support from the public.

ICIJ was founded in 1997 and is focusing on issues that do not stop at national frontiers: smuggling by multinational tobacco companies and by organized crime syndicates; private military cartels, asbestos companies and climate change lobbyists. The core staff of ICIJ is fairly small, today it is ten people, two years ago it was only five. ICIJ can also use stuff from its mother organization, the Center for Public Integrity, a kind of Watch dog organization, for data analysis, fact checking and juridical advice.

But most important: There is a network of 185 investigative journalists in 65 countries worldwide, ranging from New Zealand to China, from Norway to Peru, from Chile to Canada. It is a network you can rely on, ICIJ director Gerard Ryle told me once. You can pick up the phone and invite reporters to join a team.

That's the way I came into contact with ICIJ. I received a call from Ryle, in February 2012. He had read a report in the Spiegel I had written together with a colleague. It was on human tissue trade, a subject I have been investigating since 2006. A whistle blower had leaked thousands of internal company documents to me and that led to the Spiegel report. So Ryle invited me to join the team he was compiling for an investigation in this field. The title of our project: Skin and bones.

You all probably know about organ transplantation. But there are other human body parts used for medical needs. It is bones, tendons, heart valves, skin, fascia lata – that is the deep fascia of the thigh. Doctors use human tissue for procedures ranging from spinal reconstruction to plastic surgery, for example nose correction, often without telling their patients. Also, when

doctors order tissue, they usually do so from a catalog that lacks any information on the tissues provenance, or under what circumstances it was collected.

Organs are transplanted immediately after recovery and there is no legal market for human organs. Tissues are different. They are usually not life saving and they are not being implanted immediately. There is time to process them, sometimes sterilize them to minimize the risk of an infection in the recipient. That's the reason why human tissues turn into medical products which are sold all over the world. The biggest market for human tissues are the United States, you even have companies publicly listed on a stock exchange. A single healthy body can yield up to 200,000 Dollar worth of recyclable tissues.

From the beginning to the end our investigation took nine month. Our team looked at more than 200 companies. We talked to everyone from industry insiders and government officials to surgeons and convicted felons.

We read through thousands of court documents

regulatory reports

corporate records

and internal company memos

We analyzed data on

imports

inspections

adverse events

and accident reports

filed with the Food and Drug Administration (FDA), the US agency that oversees the human tissue trade.

What was surprising to us: The FDA declined repeated requests for on-record interviews. What was less surprising: The industry association also refused repeated requests over four months for on-record interviews. So did nearly every single company we contacted.

How did we organize our work:

Like all ICIJ teams we worked in a virtual news-room, we corresponded via skype, shared documents via a the Online-file-sharing-system box.net and exchanged ideas and updates through a mailing-list. Although our budget was limited we once managed to meet in person. That was in March 2012 in Brussels. The core team came together, it was Gerard Ryle and Kate Willson from ICIJ, reporters from Spain, South Korea, Bulgaria, Ukraine and me. In Brussels we shared our level of information and allocated tasks to everybody.

My role was to consult the team about the human tissue market, how it is organized, of course I uploaded the thousands of leaked documents to the box and other material. While working for ICIJ I was also involved with an update of a film documentary and we shared our information and material, too.

Our main findings:

There was a cooperation between the Ukraine, Germany and the US in tissue recovery and processing for the market. The German company Tutogen Medical, a subsidy of the US company RTI Biologics, had been sourcing tissues in Eastern Europe for decades through local partners. Especially in Ukraine large amounts of tissues were recovered from corpses. There were repeated allegations in Ukraine that human tissue was removed from the dead without proper consent. Some of that tissue may have reached other countries, via Germany, and may have been implanted in patients. One of our major findings is that inadequate safeguards are in place to ensure all tissue used by the industry is obtained legally and ethically.

One of the strongest stories came from a Ukrainian family. Serghei, the 19 year old son of the family, had committed suicide. The family was still under shock when collaborators of the local morgue in Kriwoj Rog came to them, submitted some papers and asked them to sign. At Sergei's funeral, his parents discovered deep cuts on his wrists. Yet they knew he had hanged himself. They later learned through a police investigation that his body parts had been recycled and shipped off as "anatomical material." The family was traumatized: "They make money with our misfortune," Sergei's father said.

The morgue in Kriwoj Rog had been cooperating with the partner of Tutogen Medical in Ukraine, the company Bioimplant. Tutogen stopped the cooperation with this morgue but Bioimplant, owned by the ministry of Health in the Ukraine, continued to cooperate with nearly twenty other morgues for tissue recovery.

(In February 2012 - a few months into our research - authorities raided a morgue in the southern town of Mykolaiv. We talked to investigators. They told us signatures were forged to make it seem like families had given their consent. There were court trials against people from the morgues but it never came to a conviction.)

Another important finding was the risk that tissue implants may mean for recipients. Contaminated tissue has been linked to at least 1,352 infections and 40 deaths in the U.S. since 2002, according to ICIJ's analysis of FDA records. Tissues from a single body are often divided up amongst multiple patients on different continents. But there is no system in place to notify the recipients if the donor body turns out to have had an infection. Body brokers have even falsified records to hide deadly infections and deaths.

The industry says the chance of contamination in patients is low. Most tissue products undergo radiation and sterilization, rendering them safer. There is little data, though, to back up the industry's claims. Companies in the US are required to report only the most serious adverse events they discover.

Our main publication came out in July 2012, in The Huffington Post. We had Media Partners in eleven countries that reprinted the story, for example in Brazil, Japan, Australia, Spain, France, Chile, Czech Republic, Argentina, Ukraine.

In Germany I had already covered the issue a lot, so we could not place the main article of ICIJ as a whole, but I wrote an update for Die Zeit.

Three months after our publication came out RTI Biologics suspended imports of human tissue from Ukraine. Voluntarily, the company said in a statement.