

Skin, bones and tissue for sale: How the dead are being used for grisly trade in human body parts

- Tissue and bone used for skin grafts, dental implants and cancer treatment taken from patients without consent
- Expose carried out by International Consortium of Investigative Journalists

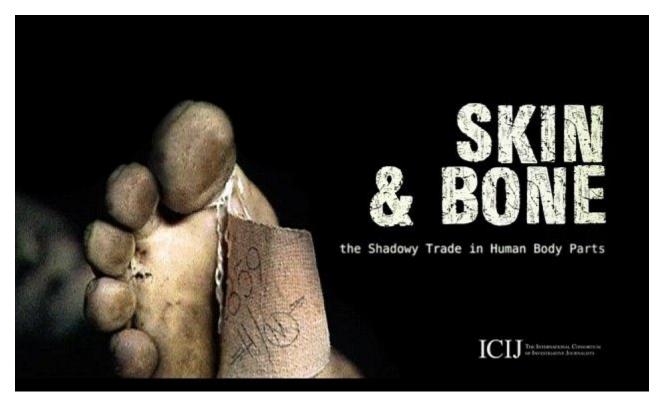
By Kate Wilson, Vlad Lavrov, Martina Keller, Thomas Maier And Gerard Ryle

On Feb. 24, Ukrainian authorities made an alarming discovery: bones and other human tissues crammed into coolers in a grimy white minibus.

Investigators grew even more intrigued when they found, amid the body parts, envelopes stuffed with cash and autopsy results written in English.

What the security service had disrupted was not the work of a serial killer but part of an international pipeline of ingredients for medical and dental products that are routinely implanted into people around the world.

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In their expose, the International Consortium of Investigative Journalists followed the trial of body parts back to the Ukraine, where many are harvested



Human skin is applied to a burn patient at Queen Astrid Military Hospital in Brussels

The seized documents suggested that the remains of dead Ukrainians were destined for a factory in Germany belonging to the subsidiary of a U.S. medical products company, Florida-based RTI Biologics.

RTI is one of a growing industry of companies that make profits by turning mortal remains into everything from dental implants to bladder slings to wrinkle cures.

The industry has flourished even as its practices have roused concerns about how tissues are obtained and how well grieving families and transplant patients are informed about the realities and risks of the business.

In the U.S. alone, the biggest market and the biggest supplier, an estimated two million products derived from human tissue are sold each year, a figure that has doubled over the past decade.

It is an industry that promotes treatments and products that literally allow the blind to see (through cornea transplants) and the lame to walk (by recycling tendons and ligaments for use in knee repairs). It's also an industry fueled by powerful appetites for bottom-line profits and fresh human bodies.



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In the Ukraine, for example, the security service believes that bodies passing through a morgue in the Nikolaev district, the gritty shipbuilding region located near the Black Sea, may have been feeding the trade, leaving behind what investigators described as potentially dozens of "human sock puppets" - corpses stripped of their reusable parts.

Industry officials argue that such alleged abuses are rare, and that the industry operates safely and responsibly.

For its part, RTI didn't respond to repeated requests for comment or to a detailed list of questions provided a month before this publication.

In public statements the company says it 'honors the gift of tissue donation by treating the tissue with respect, by finding new ways to use the tissue to help patients and by helping as many patients as possible from each donation.'

'Our Misfortune'

Despite its growth, the tissue trade has largely escaped public scrutiny. This is thanks in part to less-thanaggressive official oversight — and to popular appeal for the idea of allowing the dead to help the living survive and thrive.

An eight-month, 11-country investigation by the International Consortium of Investigative Journalists (ICIJ) has found, however, that the tissue industry's good intentions sometimes are in conflict with the rush to make money from the dead.

Inadequate safeguards are in place to ensure all tissue used by the industry is obtained legally and ethically, ICIJ discovered from hundreds of interviews and thousands of pages of public documents obtained through records requests in six countries.

Despite concerns by doctors that the lightly regulated trade could allow diseased tissues to infect transplant recipients with hepatitis, HIV and other pathogens, authorities have done little to deal with the risks.

In contrast to tightly-monitored systems for tracking intact organs such as hearts and lungs, authorities in the U.S. and many other countries have no way to accurately trace where recycled skin and other tissues come from and where they go.

At the same time, critics say, the tissue-donation system can deepen the pain of grieving families, keeping them in the dark or misleading them about what will happen to the bodies of their loved ones.

Those left behind, like the parents of 19-year-old Ukrainian Sergei Malish, who committed suicide in 2008, are left to cope with a grim reality.

At Sergei's funeral, his parents discovered deep cuts on his wrists. Yet they knew he had hanged himself.

They later learned that his body parts had been recycled and shipped off as "anatomical material."

'They make money with our misfortune,' Sergei's father said.

Awkward silence



A body is harvested for skin, which can be used in skin grafts for burns patients

During the transformational journey tissue undergoes — from dead human to medical device — some patients don't even know that they are the final destination.

Doctors don't always tell them that the products used in their breast reconstructions, penis implants and other procedures were reclaimed from the recently departed.

Nor are authorities always aware of where tissues come from or where they go.

The lack of proper tracking means that by the time problems are discovered some of the manufactured goods can't be found. When the U.S. Centers for Disease Control and Prevention assists in the recall of products made from potentially tainted tissues, transplant doctors frequently aren't much help.

'Oftentimes there's an awkward silence. They say: "We don't know where it went",' said Dr. Matthew Kuehnert, the CDC's director of blood and biologics.

'We have barcodes for our [breakfast] cereals, but we don't have barcodes for our human tissues,' Kuehnert said. 'Every patient who has tissue implanted should know. It's so obvious. It should be a basic patient right. It is not. That's ridiculous.'

Since 2002 the U.S. Food and Drug Administration has documented at least 1,352 infections in the U.S. that followed human tissue transplants, according to an ICIJ analysis of FDA data. These infections were linked to the deaths of 40 people, the data shows.

'We have barcodes for our (breakfast) cereals, but we don't have barcodes for our human tissues. Every patient... should know. It's so obvious. It should be a basic patient right. It is not. That's ridiculous.' Dr. Matthew Kuehnert, the CDC's director of blood and biologics One of the weaknesses of the tissue-monitoring system is the secrecy and complexity that comes with the cross-border exchange of body parts.

The Slovaks export cadaver parts to the Germans; the Germans export finished products to South Korea and the U.S.; the South Koreans to Mexico; the U.S. to more than 30 countries.

Distributors of manufactured products can be found in the European Union, China, Canada, Thailand, India, South Africa, Brazil, Australia and New Zealand. Some are subsidiaries of multinational medical corporations.

The international nature of the industry, critics claim, makes it easy to move products from place to place without much scrutiny.

'If I buy something from Rwanda, then put a Belgian label on it, I can import it into the U.S. When you enter into the official system, everyone is so trusting,' said Dr. Martin Zizi, professor of neurophysiology at the Free University of Brussels.

Once a product is in the European Union, it can be shipped to the U.S. with few questions asked.

"They assume you've done the quality check," Zizi said. "We are more careful with fruit and vegetables than with body parts."

Piece of the action

Inside the marketplace for human tissue, the opportunities for profits are immense. A single, disease-free body can spin off cash flows of \$80,000 to \$200,000 for the various non-profit and for-profit players involved in recovering tissues and using them to manufacture medical and dental products, according to documents and experts in the field.

It's illegal in the U.S., as in most other countries, to buy or sell human tissue. However, it's permissible to pay service fees that ostensibly cover the costs of finding, storing and processing human tissues.

Almost everyone gets a piece of the action.

Ground-level body wranglers in the U.S. can get as much as \$10,000 for each corpse they secure through their contacts at hospitals, mortuaries and morgues. Funeral homes can act as middlemen to identify potential donors. Public hospitals can get paid for the use of tissue-recovery rooms.

And medical products multinationals like RTI? They do well, too. Last year RTI earned \$11.6 million in pretax profits on revenues of \$169 million.

Phillip Guyett, who ran a tissue recovery business in several U.S. states before he was convicted of falsifying death records, said executives with companies that bought tissues from him treated him to \$400 meals and swanky hotel stays.

They promised: 'We can make you a rich man.' It got to the point, he said, that he began looking at the dead "with dollar signs attached to their parts." Guyett never worked directly for RTI.

Smoked salmon



Human skin: After being mashed up to remove moisture, some is destined to protect burn victims from life-threatening bacterial infections or, once further refined, for breast reconstructions after cancer

Human skin takes on the color of smoked salmon when it is professionally removed in rectangular shapes from a cadaver. A good yield is about six square feet.

After being mashed up to remove moisture, some is destined to protect burn victims from life-threatening bacterial infections or, once further refined, for breast reconstructions after cancer.

The use of human tissue 'has really revolutionized what we can do in breast reconstruction surgery,' explains Dr. Ron Israeli, a plastic surgeon in Great Neck, N.Y.

'Since we started using it in about 2005, it's really become a standard technique.'

A significant number of recovered tissues are transformed into products whose shelf names give little clue to their actual origin.

They are used in the dental and beauty industries, for everything from plumping up lips to smoothing out wrinkles.

Cadaver bone — harvested from the dead and replaced with PVC piping for burial — is sculpted like pieces of hardwood into screws and anchors for dozens of orthopedic and dental applications.

Or the bone is ground down and mixed with chemicals to form strong surgical glues that are advertised as being better than the artificial variety.

'At the basic level what we are doing to the body, it's a very physical - and I imagine some would say a very grotesque - thing,' said Chris Truitt, a former RTI employee in Wisconsin. 'At the basic level what we are doing to the body, it's a very physical — and I imagine some would say a very grotesque — thing,' said Chris Truitt, a former RTI employee in Wisconsin. 'We are pulling out arm bones. We are pulling out leg bones. We are cutting the chest open to pull the heart out to get at the valves. We are pulling veins out from the inside of skin.'

Whole tendons, scrubbed cleaned and rendered safe for transplant, are used to return injured athletes to the field of play.

There's also a brisk trade in corneas, both within countries and internationally.

Because of the ban on selling the tissue itself, the U.S. companies that first commercialized the trade adopted the same methods as the blood collection business.

The for-profit companies set up non-profit offshoots to collect the tissue — in much the same way the Red Cross collects blood that's later turned into products by commercial entities.

Nobody charges for the tissue itself, which under normal circumstances is freely donated by the dead (via donor registries) or by their families.

Rather, tissue banks and other organizations involved in the process receive ill-defined "reasonable payments" to compensate them for obtaining and handling the tissue.

'The common lingo is to talk about procurement from donors as "harvesting," and the subsequent transfers via the bone bank as "buying" and "selling",' wrote Klaus Høyer, from the University of Copenhagen's Department of Public Health, who talked to industry officials, donors and recipients for an article published in the journal BioSocieties.

'These expressions were used freely in interviews; however, I did not hear this terminology used in front of patients."

U.S.-government funded study of the families of U.S. tissue donors, published in 2010, indicates many may not understand the role that for-profit companies play in the tissue donation system.

Seventy-three percent of families who took part in the study said it was "not acceptable for donated tissue to be bought and sold, for any purpose."



Few Protections

Cadaver bone - harvested from the dead and replaced with PVC piping for burial - is sculpted like pieces of hardwood into screws and anchors for dozens of orthopedic and dental applications

There is an inherent risk in transplanting human tissues. Among other things, it has led to life-threatening bacterial infections, and the spread of HIV, Hepatitis C and rabies in tissue recipients, according to the CDC.

Modern blood and organ collection is bar-coded and strongly regulated — reforms prompted by highprofile disasters that had been caused by the poor screening of donors. Products made from skin and other tissues, however, have few specific laws of their own.

In the U.S., the agency that regulates the industry is the Food and Drug Administration, the same agency that's charged with protecting the nation's food supply, medicines and cosmetics.

The FDA, which declined repeated requests for on-record interviews, has no authority over health care facilities that implant the material. And the agency doesn't specifically track infections It does keep track of registered tissue banks, and sometimes conducts an inspection. It also has the power to shut them down.

The FDA largely relies on standards that are set by an industry body, the American Association of Tissue Banks (AATB). The association refused repeated requests over four months for on-record interviews. It told ICIJ during a background interview last week that the 'vast majority' of banks recovering traditional tissues such as skin and bone are accredited by the AATB.

Yet an analysis of AATB accredited banks and FDA registration data shows about one third of tissue banks that recover traditional tissues such as skin and bone are accredited by the AATB.

The association says the chance of contamination in patients is low. Most products, the AATB says, undergo radiation and sterilization, rendering them safer than, say, organs that are transplanted into another human.

'Tissue is safe. It's incredibly safe,' an AATB executive said.

There is little data, though, to back up the industry's claims.

Unlike with other biologics regulated by the FDA, agency officials explain, firms that make medical products out of human tissues are required to report only the most serious adverse events they discover. That means that if problems do arise, there's no guarantee that authorities are told.

And because doctors aren't required to tell patients they're getting tissue from a cadaver, many patients may not associate any later infection with the transplant.

On this point, the industry says it is able to track the products from the donors to the doctors, using their own coding systems, and that many hospitals have systems in place to track the tissues after they're implanted.

But no centralized regional or global system assures products can be followed from donor to patient.

"Probably very few people get infected, but we really don't know because we don't have surveillance and we don't have a system for detecting adverse events," the CDC's Kuehnert said.

The FDA recalled more than 60,000 tissue-derived products between 1994 and mid-2007.

The most famous recall came in 2005. It involved a company called Biomedical Tissue Services, which was run by a former dental surgeon, Michael Mastromarino.

Mastromarino got many of his raw materials from undertakers in New York and Pennsylvania. He paid them up to \$1,000 per body, court records show.



Dental surgeon Michael Mastromarino paid undertakers \$1,000 so he could strip dead bodies of tissue, before returning them to their families

His company stripped bodies of their bones, skin and other usable parts, then returned them to their families. The families, ignorant of what happened, buried or cremated the evidence.

One of more than 1,000 bodies that were dismembered was that of the famous BBC broadcaster and Masterpiece Theatre host Alistair Cooke.

Products made from the stolen human remains were shipped to Canada, Turkey, South Korea, Switzerland and Australia. More than 800 of those products have never been located.

It later came out in court that some of the tissue donors had died from cancer and that none had been tested for pathogens like HIV and hepatitis.

Mastromarino falsified donor forms, lying about causes of death and other details. He sold skin and other tissues to several U.S. tissue-processing firms, including RTI.

"From day one, everything was forged; everything, because we could. As long as the paperwork looked good, it was fine," said Mastromarino, who is serving a 25-to-58-year prison sentence for conspiracy, theft and abuse of a corpse.

Global Sheriff

Each country has its own set of regulations for the use of products made from human tissue, often based on laws that were originally intended to deal with blood or organs.

In practice, though, because the U.S. supplies an estimated two-thirds of the world's human-tissueproduct needs, the FDA has effectively been left to act as sheriff for much of the planet.

Foreign tissue establishments that wish to export products to the U.S. are required to register with the FDA.

Yet of the 340 foreign tissue establishments registered with the FDA, only about 7 percent have an inspection record in the FDA database, an ICIJ analysis shows. The FDA has never shut one down due to concern over illicit activities.

The data also shows that about 35 percent of active registered U.S. tissue banks have no inspection record in the FDA database.

'When the FDA registers you, all you have to do is fill out a form and wait for an inspection,' said Dr. Duke Kasprisin, the medical director for seven U.S. tissue banks. 'For the first year or two you can function without having anyone look at you.'



The parents of 19-year-old Ukrainian Sergei Malish, whose body parts were recycled into 'anatomical material' without his parents' consent

This is backed by the data, which show the typical tissue bank operates for nearly two years before its first FDA inspection.

'The problem is there is no oversight. The FDA, all they require is that you have a registration,' said Craig Allred, an attorney previously involved in litigation against the industry. 'Nobody is watching what is going on.' The FDA and industry players 'all point the finger at each other.'

Yet in South Korea, for example, the booming plastic surgery market uses FDA oversight as a selling point.

In downtown Seoul, the country's capital, Tiara Plastic Surgery explains that human tissue products 'are FDA-approved' and are therefore safe.

Some medical centers advertise "FDA-approved AlloDerm" — a skin graft made from donated American cadavers — for nose enhancement.

Le Do-han, the official in charge of human tissue for the South Korean FDA, said the country imports 90 percent of its human-tissue needs.

Raw tissue is shipped in from the U.S. and Germany. This tissue, once processed, is often re-exported to Mexico as manufactured goods.

Despite the complicated movements back and forth, Le Do-han acknowledges that proper tracking hasn't been put in place.

'It is like putting tags on beef, but I don't even know if that is possible for human tissues because there are so many coming in.'

Teaming Up

In its U.S. Securities and Exchange Commission filings, publicly traded RTI provides a glimpse of the company's size and global reach.

In 2011, the company manufactured 500,000 to 600,000 implants and launched 19 new kinds of implants in sports medicine, orthopedics and other areas. Ninety percent of the company's implants are made from human tissue, while 10 percent come from cows and pigs processed at its German facility.

RTI requires its human body parts suppliers in the U.S. and other nations to follow FDA regulations, but the company acknowledges there are no guarantees.

In 2011 securities filings, RTI said there "can be no assurances" that "our tissue suppliers will comply with such regulations intended to prevent communicable disease transmission" or "even if such compliance is achieved, that our implants have not been or will not be associated with transmission of disease."

'Two ribs, two Achilles heels, two elbows, two eardrums, two teeth' A list of tissue taken from the body of 35-year-old Oleksandr Frolov

Like many of today's for-profit tissue companies that were once non-profits, RTI broke away from the non-profit University of Florida Tissue Bank in 1998.

Internal company files from Tutogen, a Germany medical products company, show that RTI teamed up with Tutogen as early as September 1999 to help both companies meet their growing needs for raw material by obtaining human tissue from Eastern Europe.

The companies both obtained tissue from the Czech Republic. Tutogen separately obtained tissues from Estonia, Hungary, Russia, Latvia, Ukraine, and later Slovakia, documents show.

In 2002, allegations surfaced in the Czech media that the local supplier to RTI and Tutogen was obtaining some tissues there improperly. Though there is no suggestion that Tutogen or RTI or its employees did anything improper.

In March 2003, police in Latvia investigated whether Tutogen's local supplier had removed tissue from about 400 bodies at a state forensic medical institute without proper consent.

Wood and fabrics, replacing muscle and bone, were put into the deceased to make it look like they were untouched before burial, local media reported.

Police eventually charged three employees of the supplier, but later dismissed the charges when a court ruled that no consent from donors' families was necessary. Again, there was no suggestion Tutogen acted improperly.

In 2005, Ukrainian police launched the first of a series of investigations into the activities of Tutogen's suppliers in that country. The initial investigation did not lead to criminal charges.

The relationship between Tutogen and RTI, meanwhile, became even closer in late 2007, when they announced a merger between the two companies. Tutogen became a subsidiary of RTI in early 2008.

Officials at RTI declined to answer questions from ICIJ about whether it knew about police investigations of Tutogen's suppliers.

Two Ribs

In 2008 Ukrainian police launched a new investigation, looking into allegations that more than 1,000 tissues a month were being illegally recovered at a forensic medical institute at Krivoy Rog and sent, via a third party, to Tutogen.

Joseph Düsel, the Chief Prosecutor in Bamberg, said in 2009 that "what the company is doing is approved by the administrative authority by which it is also monitored. We do not currently see any reason to initiate investigation proceedings."

Nataliya Grishenko, the judge prosecuting the case, revealed during subsequent court proceedings that many relatives claimed they'd been tricked into signing consent forms or that their signatures had been forged.

However, the main suspect in the case — a Ukrainian doctor — died before the court could deliver a verdict. The case died with him.

Tutogen 'operates under very strict regulations from German and Ukrainian authorities as well as other European and American regulatory authorities,' the company said in a statement while the case was still pending. 'They have been inspected regularly by all of these authorities over their many years of operation, and Tutogen remains in good standing with all of them.'

Seventeen of Tutogen's Ukrainian suppliers have undergone an FDA inspection. The inspections are announced, according to protocol, six to eight weeks in advance.

Only one — BioImplant in Kiev — received negative feedback. Among the findings of the 2009 inspection: not all morgues could rely on hot running water and some sanitation procedures were not followed.

FDA inspectors also identified deficiencies with RTI's Ukrainian imports when it visited the company's facilities in Florida.

RTI had English translations, but not original autopsy reports, from its Ukrainian donors, FDA inspectors found during a 2010 audit. Those were often the only medical documents the company used to determine whether the donor was healthy, inspectors noted in their report.



Security services footage shows harvested human tissues in Ukraine labeled "Made in Germany".

The company told inspectors it was illegal under Ukrainian law to copy the report. But following the inspection it began maintaining the original Russian-language document along with its English translation.

In 2010 and 2011, FDA inspectors asked RTI to change how it labeled its imports. The company was obtaining Ukrainian tissue, shipping it to Tutogen in Germany, then exporting it to the U.S. as a product of Germany.

While the company agreed to change its policies, there is some indication that it may have continued labeling some Ukrainian tissue as German.

This past February, Ukrainian security services launched a raid as officials at a regional forensic bureau in Nikolaev Oblast were loading harvested human tissues into the back of a white minibus. Footage of the seizure shows tissue labeled 'Tutogen. Made in Germany.'

In this case, the security service said forensic officials had tricked relatives of the dead patients into agreeing to what they thought was a small amount of tissue harvesting by playing on their pain and grief.

Seized documents — blood tests, an autopsy report and labels written in English and obtained by ICIJ — suggested the remains were on their way to Tutogen.

Some of the tissue fragments found on the bus came from 35-year-old Oleksandr Frolov, who had died from an epileptic seizure.

'On the way to the cemetery, when we were in the hearse, one of his feet — we noticed that one of the

shoes slipped off his foot, which seemed to be hanging loose,' his mother, Lubov Frolova, told ICIJ.

'When my daughter-in-law touched it, she said that his foot was empty.'

Later, the police showed her a list of what had been taken from her son's body.

'Two ribs, two Achilles heels, two elbows, two eardrums, two teeth, and so on. I couldn't read it till the end, as I felt sick. I couldn't read it,' she said.

'I heard that [the tissues] were shipped to Germany to be used for the plastic surgeries and also for donation. I have nothing against donation, but it should be done according to the law.'

Kateryna Rahulina, whose 52-year-old mother, Olha Dynnyk, died in September 2011, was shown documents by investigating police. The documents purported to give her approval for tissue to be taken from her mother's body.

'I was in shock,' Rahulina said. She never signed the papers, she said, and it was clear to her that someone had forged her approval.

The forensic bureau in Nikolaev Oblast, where the alleged incidents happened, was, until recently, one of 20 Ukrainian tissue banks registered by the FDA.

On the FDA's website the phone number for each of the tissue banks is the same.

It is Tutogen's phone number in Germany.

• The International Consortium of Investigative Journalists is an independent global network of reporters who collaborate on cross-borders investigative stories. To see video, graphics and more stories in this series, go to www.icij.org/tissue.

WARNING, VIDEO CONTAINS VERY GRAPHIC CONTENT

Read more: <u>http://www.dailymail.co.uk/news/article-2175006/Skin-bones-tissue-sale-How-dead-used-grisly-trade-human-body-parts.html#ixzz20xv2DIWQ</u>