

SKIN & BONE

The Shadowy
Trade in
Human Body
Parts



THE INTERNATIONAL CONSORTIUM
OF INVESTIGATIVE JOURNALISTS



THE CENTER FOR
PUBLIC INTEGRITY

Table of Contents

Key Findings	3	Products Made from Tissue	7
About this Project	3	How Safe is Human Tissue?	8
Project Credits	4	Methodologies	54
Key Questions About Tissue	5	About the ICIJ & CPI	56

PART 1 **9**

Human Corpses Are Prize in Global Drive for Profits

The business of recycling dead humans into medical implants has flourished. But 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.

PART 2 **23**

Body Brokers Leave Trail of Questions, Corruption

Police in Hungary, Ukraine and the U.S. allege that tissue suppliers stole tissue and committed fraud and forgery in the drive to supply the industry with flesh and bone.

PART 3 **35**

Traceability Elusive in Global Trade of Human Parts

Poor accountability and inadequate safeguards prompt concerns among medical experts that products made from tissues taken from the dead could spread disease to the living.

PART 4 **45**

Abusing the ‘Gift’ of Tissue Donation

In the brave new world of tissue harvesting, the dead’s bones, skin, tendons and heart valves can be cut out and used to create medical devices that can be sold for profit around the world.

Go online for more about the global trade in human body parts including video, supporting documents and related stories at:
www.icij.org/tissue

KEY FINDINGS

Consent: There have been 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 now be implanted in hospital patients.

Safety: Surgeons are not always required to tell patients they are receiving products made of human tissue, making it less likely a patient would associate subsequent infection with that product.

Tracking: The U.S. is the world's biggest trader of products from human tissue, but authorities there don't seem to know how much tissue is imported, where it comes from, or where it subsequently goes.

About this Project

Skin And Bone: The Shadowy Trade In Human Body Parts was an eight-month project by the International Consortium of Investigative Journalists (ICIJ), a global network of reporters who collaborate on in-depth investigative stories that cross national boundaries

ICIJ found the business of recycling dead humans has grown so large over the past decade that you can buy stock in publicly traded companies that rely on corpses for their raw materials.

Skin and bones donated by relatives of the dead are turned into everything from bladder slings to surgical screws to material used in dentistry or plastic surgery.

Distributors of the merchandise can be found in much of the world. Some are subsidiaries of billion-dollar multinational medical corporations.

ICIJ discovered that patients aren't always told that the product they are getting originated from a corpse. This led to a more complex issue – how does the industry source the raw material it uses in its products?

Inquiries were conducted across 11 countries and the project was co-researched with National Public Radio

and Newsday (USA), the Kiev Post (Ukraine), The Daily Slovakia (Slovakia) and La Voce della Repubblica Ceca (Czech Republic).

The ICIJ's investigation relied on more than 200 interviews with industry insiders, government officials, surgeons, lawyers, ethicists and convicted felons, as well as thousands of court documents, regulatory reports, criminal investigation findings, corporate records and internal company memos.

ICIJ also conducted analysis on

registered tissue banks, imports, inspections, adverse events, and deviation reports filed with the Food and Drug Administration, the US agency that polices the trade. ICIJ obtained the data through records requests to the FDA.

Palantir donated the use of software and assisted reporters in analyzing and visualizing data, as well as provided interactive and still graphics for ICIJ and partner publications.

The project was unveiled at the Google Ideas INFO Summit. ■

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The Kiev Post (Ukraine)

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El Puercoespín (Argentina)

The Daily (Czech Rep.)

La Nación (Argentina)

Key Questions About Human Tissue

What if I want to donate organs but not tissue?

Countries have widely varying laws surrounding organ and tissue donation — a few have no laws at all. In many countries, every citizen is considered a donor unless he chooses to opt out while he is still alive. In the United States, citizens must specifically consent. But each U.S. state has its own laws determining what that really means. Donate Life America offers a great resource for anyone seeking to register as an organ or tissue donor — or anyone who wants to define what the gift should be.

Companies can make a profit from my body. But aren't I saving lives?

Tissues improve the quality of peoples' lives. And in some cases, yes, they even save lives. Heart valves are in short supply, for instance. Skin is used as a cover for severe burns — it works better than any synthetic covering when those burns cover a majority of the body — and to help slow-healing diabetic



[Video: Skin and Bone](#)

foot ulcers. Corneas can be used to help someone see again. Bone can be milled into implants that correct spinal deformities.

But tissue is also used in a number of cosmetic surgeries such as fattening lips or shaping a new nose. Skin can be used as an injectable to fill fine lines and wrinkles.

Should I be concerned about safety?

We can't say for sure, because infections are not always tracked effectively. And it's hard to determine in most cases whether an infection resulted from a tissue graft or from, say, the scalpel the surgeon used

in the operation. But the industry estimates that infections are rare. And we haven't found information that disagrees with that.

Risk of infection depends on the type of tissue you receive. Most bone used in dental and other general surgery is sterilized. But some tissue can't be industrially sterilized, such as "fresh" bone and tendon grafts, corneas, veins or heart valves. In those cases, the public largely relies on donor screening to avoid transmission of disease or bacteria.

Can I find out about the tissue bank in my area? Whether it's been inspected, reported any adverse events or accidents, or been involved in any recalls?

The FDA keeps a registry of tissue banks that do business in the U.S. That includes everything from sperm banks to laboratories that run tests on stem cells. You can check if the bank has been inspected, but you would need to file a records request if you wanted to read the concerns FDA auditors might have documented.

It's harder to find out if a bank has reported adverse events or accidents. Many adverse events are

filed voluntarily, so the FDA won't release those. But some tissues are regulated as a medical device rather than a biologic. Reports of those adverse events can be found in the FDA's Manufacturer and User Facility Device Experience.

Reports of errors and accidents in a tissue bank's manufacturing process are not available on line. But they are on public record, so you can file a records request.

Finally, recalls are reported either as biologics or as medical devices and are available at the FDA website.

I had orthopedic surgery. Did I receive tissue from a cadaver?

Maybe. Doctors are not required to inform patients when they use human tissue during an operation. So ask your doctor what product was used. You can probably find it at the FDA.

How can I track the source of the human tissue I was implanted with?

We don't know.

Do you have any other questions about the use of human tissue as medical devices or the global trade of this material? Get in touch via investigations@icij.org. ■

PRODUCTS MADE FROM HUMAN TISSUE

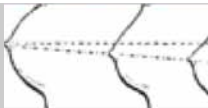
Dental implants



Cruciate ligament reconstruction



Breast reconstruction after cancer



Orthopedic or spinal surgery



Penis enlargement



Bone grafts



Smoothing out wrinkles



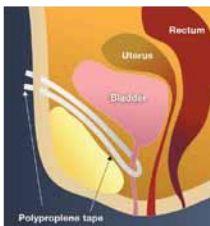
Covering for diabetic foot ulcers



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.

Human Corpses Are Prize in Global Drive For Profits

By Kate Willson, Vlad Lavrov, Martina Keller, Thomas Maier and Gerard Ryle

Published Online: July 17, 2012

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.

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 com-



The business of recycling dead humans into medical implants is flourishing.

pany, 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.

In the Ukraine, for example, the security service believes that bodies passing through a morgue in the Nikolaev district, the gritty ship-building 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-than-aggressive 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 par-

ents 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

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



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

One of the weaknesses of the tissue-monitoring system is the secrecy and complexity that comes with the cross-border exchange of body parts.

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.

"Often times there's an awkward silence. They say: 'We don't know where it went,'" said Dr. Matthew Kuehnert, the CDC's director of Blood, Organ, and other Tissue Safety.

"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.

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 cov-

er 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 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.

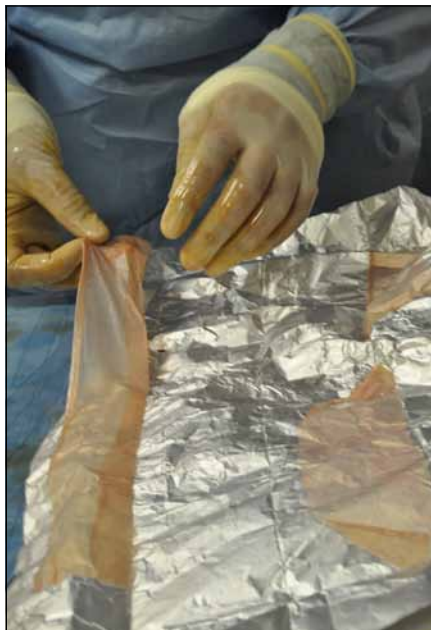
“Since we started using it in about 2005, it’s really become a standard technique.”

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.



Human skin in use at Queen Astrid Military Hospital in Brussels.

Photo: Mar Cabra

“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.”

A 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

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 high-profile disasters that had been caused by the poor screening of do-

Firms that make medical products out of human tissues are required to report only the most serious adverse events they discover.

nors. 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 ICLJ during a background interview last week that the "vast majority" of banks recovering traditional tissues such as skin and bone are ac-

credited 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.

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

“The problem is there is no oversight.... Nobody is watching what is going on.” The FDA and industry players “all point the finger at each other.”

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-tissue-product 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.”

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."

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 foren-

sic 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 — Bio-Implant 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.

The company told inspectors it was illegal under Ukrainian law to copy the report. But following the inspection it began maintaining the



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

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. ■

This story was co-reported by National Public Radio (USA).

Body Brokers Leave Trail Of Questions, Corruption

*By Kate Willson, Vlad Lavrov,
Martina Keller and Michael Hudson*

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IN APRIL 2003, Robert Ambrosino murdered his ex-fiancée — a 22-year-old aspiring actress — by shooting her in the face with a .45-caliber pistol.

Then Ambrosino turned the gun around and killed himself.

Soon after, Ambrosino's corpse entered the United States' vast tissue-donation system, his skin, bones and other body parts destined for use in the manufacture of cutting-edge medical products.

But before they entered the system, Michael Mastromarino, owner of a New Jersey-based tissue recovery firm, needed to solve a couple of problems.

He didn't want to have to report that Ambrosino had perished in a murder-suicide. And he didn't want anyone to know that Ambrosino's family hadn't given permission for his body to be used for tissue donation.

Mastromarino solved both prob-



Michael Mastromarino, serving a sentence of up to 58 years, describes himself as a human tissue broker rather than a body thief. Photo: ICIJ

lems the same way: He lied.

He claimed Ambrosino died in a car accident. And he claimed that Ambrosino's family had agreed to donate his tissue before the rest of his remains were cremated.

Mastromarino was the leader of a now-infamous human tissue traf-

ficking ring that fed an international trade in body parts. Along with tissues from Ambrosino's corpse, he stole parts from grandmothers, electrical engineers, and factory workers, as well as from the remains of famed journalist Alistair Cooke.

The disgraced dental surgeon from Brooklyn supplied the raw material for products used for a host of surgical operations — from knee repair to plastic surgery and cosmetic implants. He was a ground-level player in an industry that makes its profits by harvesting human tissues mostly from the United States, but also from Slovakia, Estonia, Mexico, and other countries around the world. One of Mastromarino's top buyers was Florida-headquartered RTI Biologics, a processor of American, Canadian and Ukrainian body parts that trades among the high-tech companies on the NASDAQ stock exchange.

Years after Mastromarino was sent to prison and the publicity in his case quieted down, his story has been given new life by a lawsuit filed in a Staten Island courthouse. New York Supreme Court Judge Joseph J. Maltese has given the green light for RTI to stand trial Oct. 22 in a civil case that will delve into what the company knew — or should

have known — about Mastromarino's body snatching.

Evidence already filed in court raises questions about whether RTI was simply a victim of Mastromarino's fraud, or whether it eschewed common sense in favor of its bottom line. An investigation by the ICIJ shows that the evidence in the case — and in other body-stealing scandals across the globe — also raises larger questions about the conduct of an industry that recycles more than 30,000 human bodies each year.

Police in places including Hungary and Ukraine, and North Carolina and Alabama in the U.S., have alleged that tissue suppliers stole tissue, committed fraud and forgery, or took kickbacks to pad their pockets. These cases suggest that Michael Mastromarino wasn't the only body wrangler who has bent or broken the rules in the drive to supply the industry with flesh and bone.

A Fantastic Product

Mastromarino, now 49, is doing time at a maximum-security prison outside Buffalo, N.Y., serving a sentence of up to 58 years. He describes himself more as a human tissue broker than a body thief.

"This is an industry. It's a com-

modity. Like flour on the commodity exchange. It's no different," Mastromarino said. "I cut some corners. But I knew where I could cut corners. We were providing a fantastic product."

For more than three years until his crimes came to light in late 2005, Mastromarino's firm supplied bones and other tissue to RTI's nonprofit subsidiary, RTI Donor Services, and four other U.S. companies.

Mastromarino was familiar with RTI's operation from his previous career as one of the busiest dental surgeons in Manhattan. He regularly used products derived from cadaver bone on his patients and, in that capacity, he had signed a consultancy agreement with the company in 2000 to help further refine RTI's products.

But Mastromarino's personal life was falling apart. He started injecting prescription painkillers to sooth an old football injury, became an addict and got busted for drug possession. He tried rehab three times before giving up his medical license.

Familiar with the industry and good with a scalpel, Mastromarino opened his own human tissue recovery company. He called it Biomedical Tissue Services.

The process was easy. Mastroma-

rino filled out a form downloaded from the website of the Food and Drug Administration, the agency that regulates the industry in the U.S.

He didn't have to wait for the FDA to inspect his facilities. He began supplying body parts right away — with more than a little help, he said, from an industry leader, RTI Donor Services.

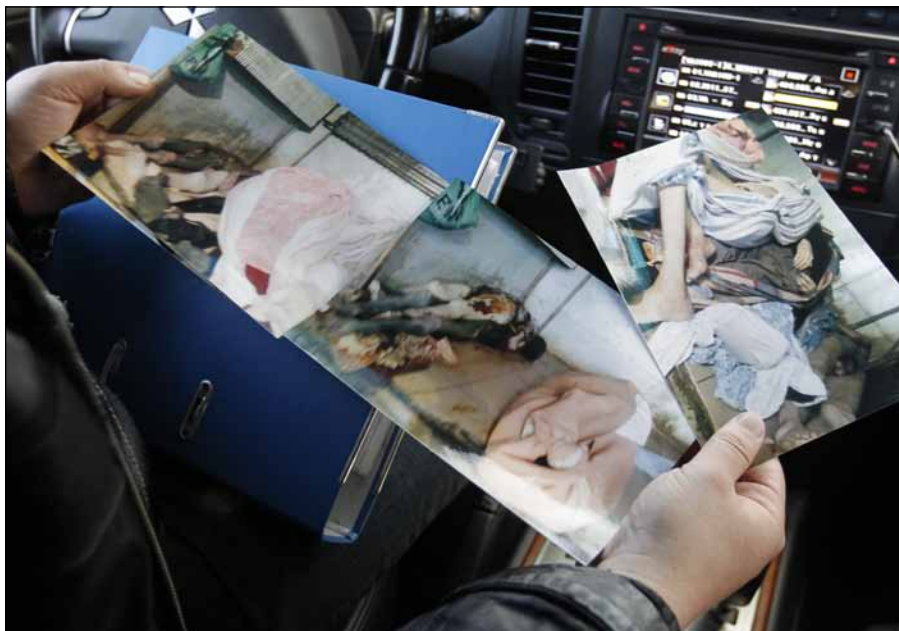
"RTI set me up," Mastromarino testified in a pending civil case. "They then said, 'Listen, we can get into your business, we can get you started, we can open up your own business.'"

'Santa's Naughty List'

The parties signed a supply contract in March 2002.

Not long after, Mastromarino's colorful language and short fuse led to complaints from RTI staff. There were also rumors about his alleged involvement with organized crime, according to testimony of Caroline Hartill, RTI Donor Services' vice president of quality assurance.

Court documents outline that RTI executives were concerned enough to hire a lawyer to run a background check on their new business partner.



Dmytro Smyrnov, owner of a funeral home, shows photographs he took inside NIKI morgue in southern Ukraine after he grew suspicious of its activities. Photo: Konstantin Chernichkin/Kyiv Post

“The good doctor has been on Santa’s naughty list for quite some time,” the lawyer, Jerome Hoffman, wrote in December 2002. “I would strongly encourage you not to do business with someone that has this kind of resume.”

A few weeks later Hoffman further urged RTI to give Mastromarino “the required 60 days notice

under the current contract and not sign a new contract.”

RTI didn’t heed the lawyer’s advice.

Instead, on Feb. 11, 2003, Caroline Hartill signed an amended contract with Mastromarino’s firm.

In the new contract, his name was replaced with a freshly licensed doctor who lived in another state

and with whom Hartill had never spoken. The doctor served as the medical director of Mastromarino's firm — according to the signature on paper at least.

Hartill testified in the pending civil case that the amended agreement was simply a routine part of accreditation with the American Association of Tissue Banks, an industry body that oversees some of the biggest tissue banks in the U.S. She said her company wanted the medical director to take Mastromarino's place on the contract because RTI determined it “would like to have more direct interaction with some of the other key principles [sic].”

RTI discounted the law firm's concerns, she said, because if Mastromarino had “turned his life around, then who was I to pass judgment on him?”

Mastromarino recalls events differently. He testified Hartill and another RTI executive called him confidentially. They worried about competitors discovering his background and using it against the company, they said. And that's why, Mastromarino said, his name came off the contract.

“Okay, whatever you guys want to do to make it comfortable,” Mastromarino told them, according to

a deposition he gave in the current civil case.

The company refused interview requests from ICIJ and did not respond to detailed questions provided more than a month before publication.

Reasonable Fees

RTI turns to corpse wranglers for a simple reason: It needs dead bodies to turn a profit.

“We cannot be sure that the supply of human tissue will continue to be available at current levels or will be sufficient to meet our needs,” RTI warned stockholders in securities filings. “We expect that our revenues would decline in proportion to any decline in tissue supply.”

And it isn't alone.

More than 2,500 companies registered with the U.S. government rely to varying degrees on the fees they charge for crafting implants made from human tissue.

The world's largest human-tissue bank, Musculoskeletal Transplant Foundation, took in nearly \$400 million in revenues in 2010.

MTF is set up as a tax-exempt nonprofit, like most organizations that recover the tissue from donors located through hospitals, funeral

“There are too many loopholes. There are too many temptations. There’s too much money out there. This industry is out of control.”

homes and morgues. Most recovery outfits supply processing companies like RTI, which clean the pieces and mill them into usable implants. The processing companies in turn distribute them directly to hospitals or use an outside vendor such as medical device giant Zimmer to ship them around the world.

Players bid for exclusive access to U.S. donors. For example, medical device company Bacterin announced last year that it “successfully secured rights of first refusal of human tissue with multiple recovery agencies.”

Competition has spawned bitter court battles. MTF sued Bacterin last year for hiring former employees who, the lawsuit alleged, used their inside knowledge to pitch a rival bone product to MTF customers. “The very foundation of MTF’s business is under direct attack,” MTF argued in its complaint.

Publicly traded NuVasive sued MTF and its partner Orthofix, accusing it of infringing on a patent for stem cell-laced bone implants.

And nonprofit LifeNet Health sued Zimmer over reimbursement fees for processing bone plugs.

RTI gets tissue directly through its nonprofit subsidiary, RTI Donor Services, and has also obtained tissue from other nonprofit tissue banks in at least 23 states.

The Alabama Organ Center is one of RTI’s suppliers. It was embroiled in scandal this spring when its second-in-command, Richard Alan Hicks, pleaded guilty to accepting kickbacks from a funeral home in exchange for tissue recovery contracts.

“There are too many loopholes. There are too many temptations. There’s too much money out there,” Hicks’ attorney Richard Jaffe told ICIJ in June. “This industry is out of control.”

The University of Texas Health Science Center at San Antonio has also recovered tissue for RTI. Its contract includes a fee chart - attaching different prices to the same tissue based on the donor’s age. RTI reimburses the recovery bank \$1,755 for a 20-year-old femur; but

\$553 for the same bone from an 80-year-old.

In 1984 Congress passed the National Organ Transplant Act, making it illegal to buy and sell human organs and other human tissues. But it allowed charging “reasonable” fees for recovering, cleaning and distributing those parts.

Younger tissue is stronger and can be more lucrative for tissue processors because it can be used for higher-value grafts. Neither RTI nor the University of Texas responded to repeated requests for clarification about why the same tissues would carry such varying fees.

ICIJ turned to Christina Strong, a lawyer for organ procurement organizations (OPO) and tissue banks including tissue giant MTF. ICIJ asked whether there could be any reason other than the quality of the tissue itself for a bank to pay more for younger tissue.

“I have not found a satisfactory answer that makes me like this,” she said, pointing to the contract. “I do not like this. I would say to my OPO, ‘Don’t sign that.’ “

Strictly Confidential

With so much competition for American cadavers, some companies

seek raw material overseas. That’s created a fertile market in Eastern Europe for body brokers and other middlemen who can help supply the tissue trade.

One of the middlemen was Igor Aleschenko, a Russian coroner working in Ukraine. In coordination with Ukraine’s ministry of health, he launched BioImplant, a state-owned tissue procurement center to supply Tutogen, a German medical products company.

Bioimplant supplied Tutogen with tissue. But Tutogen executives raised internal questions as early as 2001 about whether it should pull out of Ukraine, according to an internal memo marked “Strictly Confidential!!!!”

Aleschenko was asking for more and more money to play the role of intermediary between the regional satellite morgues around Ukraine and Tutogen in Germany.

“The flow of money is difficult to track,” the memo read. “Direct control over our resources is impossible.”

Staying in Ukraine would be high-risk, the authors determined.

“We can’t control the activities of the middlemen, and commitments are not being honored,” the memo said.

But the relationship did not stop.

Over time, 25 Ukrainian morgues registered with the FDA, each listing Tutogen's German phone number on its registration forms. Since 2002, BioImplant and Tutogen have collectively exported to the United States 1,307 shipments of tissue — mostly bone, skin and fascia sent from Germany.

Families in Kiev first began complaining to police in 2005 that a morgue that was supplying Tutogen's needs was taking tissue without proper consent. The criminal case was closed after an initial investigation. Prosecutors determined that, under Ukrainian law, they couldn't prove a crime had been committed if they couldn't prove that the tissue had been transplanted into someone, court records show.

Three years later Ukrainian police investigated another Tutogen supplier — this time in central Krivoy Rog. Those charges were dropped after the director of the morgue died while the jury deliberated in his



An x-ray of an exhumed body stripped of body parts with PVC pipe in place of leg bones.

criminal trial. Then in February of this year, police raided the Nikolaev morgue in southern Ukraine.

Some families claimed they were tricked, pressured or threatened into consenting. Police said in some cases signatures had been forged.

Aleschenko has reportedly slipped out of Ukraine for his native Russia. The Ministry will not respond to questions about his whereabouts.

Roman Hitchev, the founder of a major Bulgarian tissue bank and now president-elect of the European Association of Tissue Banks, said he was invited to Ukraine a few years ago at the request of the

regional government in Odessa. Officials wanted to operate a bank similar to that of Tutogen suppliers in Kiev. Hitchev said he left, unconvinced.

“They didn’t have legal infrastructure, laws. Regulations were insufficient,” he said. “There was too much vagueness, too much uncertainty concerning who’s responsible in terms of control, traceability. I don’t like what I saw, and I just walked away.”

Clean Inspections

The market for fresh bodies in former Soviet republics was alluring enough that even Michael Mastromarino — the New York dental surgeon turned body broker — tried to get in on the action.

He had connections in Kyrgyzstan. He flew there to meet with a top prison official. The official winced and dined him, Mastromarino said, and promised to sell him the bodies of executed inmates.

Mastromarino went home, energized at the prospects for new supply and revenue streams. He asked the FDA about importing tissue from the country.

The FDA was concerned about the risk that tissues harvested from

Kyrgyzstan might carry Creutzfeldt-Jakob disease, a fatal neurological disease akin to Mad Cow disease.

It gave Mastromarino an answer he didn’t want to hear: “No.”

So he had to be satisfied with his domestic sources of bodies. For a time, that was fine. Business was good, and he managed to avoid too much scrutiny from his buyers or regulators.

During audits of Mastromarino’s company by the FDA and RTI, no one tried to verify whether consents obtained from donors’ families were legitimate. Consents were often marked as having been taken by phone. U.S. law requires telephone consents be recorded, but no one double-checked to see if he was actually recording the telephone consents — or even getting them at all.

A Pennsylvania grand jury later condemned the entire inspection process. “If the lies in the records claimed compliance with regulations, that apparently was sufficient,” its 2007 findings read.

Even as Mastromarino’s company was passing inspections and booking profits, outsiders raised concerns about his business practices. Maryann Carroll, director of the New Jersey association of funeral directors, complained to RTI

that Mastromarino was approaching funeral homes using RTI letterhead.

“Maryann feels like this reimbursement is excessive and looks like he’s buying donors,” an RTI employee wrote executives, according to undated correspondence detailed in court records. “She claims that if the press gets ahold of this story and slams the donation, then RTI will be dragged into this and her association will state that this is the second time that we were notified and did nothing.”

RTI’s nonprofit Donor Services unit signed a new contract with Mastromarino in June 2005.

RTI didn’t know at the time it signed the new contract, the company later said, that criminal investigators had begun looking into Mastromarino’s operations.

Pizza Parlor

RTI wasn’t the only big company wanting to do business with Mastromarino.

In August 2005, LifeCell Corporation, a provider of skin grafts for burns, plastic surgery and bladder slings among other procedures, invited Mastromarino to its headquarters in New Jersey. It told him it

could pay close to \$10,000 per body if he could supply the skin from at least 400 donors a year, according to a copy of the presentation. That could have been worth millions of dollars a year to Mastromarino.

Two weeks after making its pitch, LifeCell received a letter from the Brooklyn District Attorney. Police in New York had been investigating Mastromarino’s body-stealing ring for months, after discovering forged consent forms at a Brooklyn funeral home. The DA asked LifeCell to forward any information it had relating to Mastromarino’s firm.

LifeCell did not respond to specific questions posed by ICIJ. In a statement the company said “It was LifeCell’s extensive donor review process that detected irregularities with Biomedical Tissue Services consent documents in September 2005.”

On Sept. 28 — three weeks after prosecutors asked for LifeCell’s records — Dr. Michael Bauer was clearing donor charts for LifeCell. He had always handled the donors provided by Mastromarino’s firm. But he had never tried to independently verify information. He was unaware, he later said, of the ongoing police investigation, but that night something made him do what

he'd never done before. He tried calling the number for one of the physicians listed in a donor file.

He got a pizza parlor instead.

In the scandal that followed, LifeCell, RTI, Tutogen, Lost Mountain Tissue Bank and Central Texas Blood and Tissue recalled a total of 25,000 products — 2,000 of which had been sold overseas to Australia, South Korea, Turkey, Switzerland and other countries.

Live Fast, Die Early

Mastromarino's case brought a spate of bad publicity to the industry. The unwelcome attention flared up again in August 2006, when a similar case broke in North Carolina.

Philip Guyett had been working in the tissue industry for more than a decade, starting in California, then branching out to Nevada and, eventually, North Carolina.

Along the way, Guyett discovered that the best way to find young, healthy corpses was by trolling county morgues and funeral homes in lower-income locales with high crime rates, or by targeting cities like Las Vegas, where young people act stupid and die early.

Like Mastromarino, Guyett

smoothed the process of selling off body parts with creative record keeping. He forged information on donor files, in one case selling hepatitis-infected tissue with a clean vial of blood from a different corpse.

"It's ridiculous. I should never have been able to start a recovery business," he told ICIJ in a recent interview in prison.

"I submitted the form online and in three days I was an official recovery tissue bank registered with the FDA," he says in a book written about his career. "It's harder to sell a hot dog on the street than it was to recover transplant tissue."

Guyett pleaded guilty to three counts of fraud and is serving eight years in a federal prison.

The Mastromarino and Guyett cases prompted U.S. Senator Charles Schumer, a New York Democrat, to push legislation to help rein in the tissue-processing industry. The proposal would have required that new tissue banks meet minimum standards and undergo regular inspections by the FDA. It would also have required the federal government to define "reasonable" fees — a change companies tell shareholders could endanger future revenue.

His bill died because of hard lobbying by the industry, Schumer said. “They said it wasn’t needed. They said that ‘Everything is under control,’ but I had real doubts,” he recalled. “The bottom line here is, what we saw happen in the Brooklyn funeral home could well be happening in lots of other places both here and abroad, and there’s no real protection.”

Mastromarino agrees.

“Nothing is going to change,” he said. “There are too many people making too much money.”

Pointing the Finger

After pleading guilty to avoid a possible 8,673-year prison sentence at trial, Mastromarino told prosecutors that his buyers — RTI, Tutogen and LifeCell — were not simple victims of his crimes. “Just look at how it works,” he told them.

Prosecutors said they didn’t find evidence to corroborate his claims. But families of the desecrated dead are now pressing civil charges accusing RTI of negligence — “not so much exactly what they knew, but what they should have known,” plaintiffs’ lawyers explained to the judge during the lawsuit’s pre-trial combat.

If the case does make it to trial, as scheduled, in October, Mastromarino’s story is expected to be a centerpiece of the plaintiffs’ evidence.

Important enough to the plaintiffs’ case, in fact, that lawyers for RTI Biologics fought to have his testimony thrown out. Mastromarino had already pleaded guilty to defrauding RTI and Tutogen, attorney Nancy Ledy-Gurren told Judge Maltese. He can’t turn around and point the finger at them now, she said.

Judge Maltese disagreed.

“You basically want to muzzle Mastromarino from saying anything that involves what your clients said to him — that dialogue that raises the specter of ‘What did they know and when did they know it?’” the judge told the company’s lawyers during hearings last fall.

In the judge’s view, just because the district attorney never prosecuted the executives from the bigger companies doesn’t necessarily mean they didn’t “participate in an enterprise.”

At the least, the judge said, the victims’ families have a right to argue: “They should have known. I mean, how could they be so naive?” ■

This story was co-reported by National Public Radio (USA).

Traceability Elusive In Global Trade of Human Parts

By *Kate Willson and Mar Cabra*

Published Online: July 19, 2012

THE KENTUCKY MAN died in an off-road vehicle accident last year. His liver and kidneys helped save three dying patients in his home state. Musculo-skeletal grafts taken from his heart, skin and bones were used in medical products used to improve the lives of 15 people around the country.

But soon after the transplants, the U.S. Centers for Disease Control and Prevention (CDC) learned the organ recipients had contracted hepatitis C. It turned out the Kentucky donor had a history of substance abuse and had served prison time. The tissue bank that recycled his remains, the CDC said, had screwed up the usual testing done to verify that tissues and organs were safe.

The CDC's Office of Blood, Organ, and Other Tissue Safety de-



Ukrainian security services seized harvested human tissue labeled “Tutogen. Made in Germany” in February.

ployed a team of “shoe-leather epidemiologists” to track down the tissue before someone else got sick. Unlike hearts and other organs — or blood products that come with a unique barcode — there’s no easy way to track down tissue.

The U.S. government neither knows where imported tissue originally comes from nor where exported tissue ultimately goes.

Instead the team found tissues one-by-one, calling hospitals and chasing down doctors. It took nearly a month to locate all the surgeons who had implanted tissue into 15 people. A child, later found to have hepatitis C, had received an infected heart vessel patch before the tissue recall began.

In some cases, inconsistent or non-existent record keeping prevents medical sleuths from ever finding potentially infected tissues. In one major case that played out in 2006, the U.S. Food and Drug Administration and five tissue companies moved to recall 25,000 tissues taken illegally from U.S. donors without proper consent or testing. Eight hundred of the tissues shipped overseas were never found.

The trade in human tissues is virtually untraceable at a global level. Poor accountability and inadequate safeguards have prompted concerns among medical experts that products made from bone, skin, tendon and other tissues taken

from the dead could spread disease to the living — putting patients who receive tissue implants in dental surgery, breast reconstruction and other procedures at risk.

Little has been done to address this problem, despite U.S. government reports that have raised red flags for the past 15 years — and despite continuing concerns by the CDC and the World Health Organization.

Lack of Transparency

The United States is home to the human tissue industry's largest players and provides as much as two-thirds of the world supply. But the U.S. government neither knows where imported tissue originally comes from nor where exported tissue ultimately goes.

Transplants of hearts, lungs, kidneys and other intact organs are tightly monitored because organs have to be a near-exact physical match and move immediately from donor to recipient. Hearts and oth-

er organs are charted with unique identification numbers that trace back to their donors.

By contrast, cartilage, bone and skin can be stored for months or years and shipped from place to place. Tissues aren't given standard identification numbers that allow health authorities to track them.

Some health experts have proposed — without success — that the U.S. and other countries adopt a barcoding system that would allow them to track tissues across state and national borders. It wouldn't be difficult, and it wouldn't be too costly either, they say.

“If you think of Wal-Mart, they pass through millions of products that are scanned,” said Reena Mahajan, a CDC investigator who worked on the case of the hepatitis-infected Kentucky donor. “If they had a recall, it would be very easy.”

Without the ability to systematically track products made from human tissues, officials can't respond efficiently if infected tissue is recalled. Nor can authorities assure tissue has been taken legally — or from countries with low risk for deadly infections such as Creutzfeldt-Jakob disease, the undetectable human equivalent to mad cow disease.

A pilot program implemented in the United States to follow the traffic of tissue products showed promise. But without industry support or a federal mandate, the program died. On a global scale, the World Health Organization has tried for years to collect data on the global trade. The effort collapsed when most countries — including the United States — failed to provide any data. Now the WHO has refocused efforts on trying to convince countries why they should care.

Mar Carmona, part of a two-person team trying to investigate the issue for the WHO, says the lack of participation from the U.S. helped cripple the program. “If you don't have the U.S., and they're the biggest country,” she said, getting a sense of the global picture is almost impossible.

Carmona's boss at the WHO is Dr. Luc Noël.

“I am not sure anyone has complete and precise tissue banking activity data for the USA. I only have estimations,” Noël said. And without traceability — without transparency — the trade is vulnerable to unchecked infection and illicit networks in a way organs are not. “You store, you ship, you can blur

the tracks,” he said. “It fits into the legal and illegal trade without much difficulty.”

FDA: “It Doesn’t Ring a Bell”

The United States allows companies to import tissue provided the donors are not from countries, such as the United Kingdom, with a history of mad cow disease. It sets no limits based on a country’s quality of transparency or human rights record. So England is out, but Ukraine is in.

In Ukraine, police have uncovered what they believe to be cases of illegal tissue recoveries that bring into question the safety and oversight of material that is regularly imported into the United States.

U.S. regulations do nothing, however, to address the potential for improperly obtained body parts, said an official with the FDA, the agency tapped to police the trade. They only focus on “safety and efficacy. They do not have anything to do with what’s going on in the other countries. Our regulations and our guidance would not address something like that.”

Nor does the FDA know where all human tissue is coming from. Not all imports are clearly marked

as human — or even as tissue. Instead, shipments come in under vague import codes such as “Orthopedic Implant Material.” Imports are logged into the system with a “country of origin.” But that doesn’t always lead to the source country. For example, Ukrainian tissue has been sent to facilities in Germany for processing or storage and exported to the U.S. as a product of Germany.

The FDA last year required Florida-based RTI Biologics to change its practice of identifying tissue originating in the Ukraine as German. The company bought out Germany-based Tutogen in 2008 after a long trade partnership. BioImplant — RTI’s Ukrainian supplier — has since begun exporting significant amounts of tissue to Florida directly from Ukraine.

Without being able to identify the true country of origin, officials might not connect cases of illicit tissue harvesting with products distributed in the United States — if they were even aware of such cases.

FDA officials said they were unaware of investigations carried out in Ukraine. Dozens of families complained their loved ones’ tissues were taken illegally in morgues



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.”

“There is no good traceability system right now, no barcoding, we don’t have surveillance, just shoe-leather epidemiology.”

FDA officials spoke on background, but in the presence of agency press officers. They refused previous and subsequent requests to speak on record.

Broken Chain

Companies in the U.S. distribute more than 2 million tissue products a year. These distributors should be able to track tissue from donor to hospital buyer if something goes wrong. After that, it’s the hospital’s responsibility — although not by law — to assure traceability continues to the recipients.

The doctor who implants the tissue can choose to fill out a postcard and send it to the tissue manufacturer, noted Scott Brubaker, chief policy officer of the industry group the American Association of Tissue Banks. “But this practice is voluntary and compliance is sketchy,” he wrote in a book to be published this summer.

Brubaker pointed to increasing difficulties that face compa-

nies trading tissue cross-borders. “Tracking capabilities need to be ensured particularly where there is the possibility of importation into one country and then redistribution to others,” he wrote in a report prepared as part of a 2011 conference about the global tissue trade. “For the exporter, traceability ends with the first stop in the chain of custody; the final disposition of grafts can remain unknown.”

Surgeons are not required to inform tissue companies when they use a graft or when a patient gets sick following a transplant. And even if they do hear about an infection, the companies are required to report only the most serious to the FDA. Experts suspect infection rates are low, but no one really knows.

“There is no good traceability system right now, no barcoding, we don’t have surveillance, just shoe-leather epidemiology,” said Dr. Matthew Kuehnert, director of the CDC’s blood and biologics unit. “Without surveillance, you can’t say anything.”

Between 1994 and 2007, authorities issued recalls for more than 60,000 tissue grafts. But because doctors aren't required to tell patients that the medical device is human, patients might not connect a subsequent infection with the graft itself.

"If the clinician hasn't explained the patient got human tissue, how do you explain there was a recall?" asked Kuehnert. "Physicians say they don't want to test the patients. We ask, 'Why not?' They say, 'I don't think they realized they got an allograft. So how do I explain why they need HIV or hepatitis testing done?'"

Tissue can be infected with cancer, bacteria, fungus, tuberculosis, HIV, even rabies. Scariest of them all perhaps is Creutzfeldt-Jakob disease, which can incubate undetected in a body for decades. CJD attacks the nervous system and is always deadly.

Dozens died in the 1980s and 1990s from CJD-tainted tissue. In response, the FDA forbids companies from selling medical products in the U.S. made from tissues imported from the European Union and other regions where mad cow disease had emerged. U.S. companies can still obtain tissue from

countries deemed low risk, such as Slovakia. Then they can distribute it in places outside the United States.

CJD is a known unknown. Of even greater concern are diseases that have yet to be discovered.

"I worked in the AIDS era. It was a new virus; no one knew much about it," said Dr. Duke Kasprisin, who has worked in the blood and tissue industry for decades. "We always have a certain squeamishness that something like that can occur again, that there's some new virus on the horizon that we're not thinking about today and wouldn't recognize it."

"You're only as good as the current set of infections," Kasprisin added. "We're ... trying to make sure we're not dealing with something different, something new, something transmissible."

Economist Angelo Ghirardini with the Italian Transplantation Center developed a national system to trace organs more than a decade ago. He followed that in 2008 with a way to track other human tissues such as bone, skin and veins. From his office in Rome, he proudly displays the real-time software that follows activity of Italy's 34 tissue banks.

Using a unique identification code, Ghirardini can tell you where a piece of tissue is at any given time — all the way from donor to recipient. His team is part of a consortium working to create a common coding system for the European Union's 27 countries.

"It's a priority," said biologist Deirdre Fehily, a member of the Italian team. "It's seen as a primary way of improving safety ... and also addressing ethical issues. Because if you can trace to the origin, you can investigate consent issues."

The system is required by law. But with so many languages and governments to accommodate, it's running behind schedule. The team anticipates the program will be live by 2014.

Europe and the U.S. took different approaches to regulating products made with human parts. Most European countries limit the number of banks per region based on a population's need. The United States does much the same thing with life-saving organs. But regulations are less restrictive with the other human remains.

"The U.S. early on in the history allowed profit making," Fehily explained. "Can you imagine in the States someone saying, 'Con-

necticut can only have three bone banks'? If someone wants to start a bone bank, they start it."

Grim Outlook

The Government Accountability Office (then called the General Accounting Office) first reported on the lack of traceability in the budding U.S. tissue industry in 1997. "The current tissue-tracking system is inadequate to notify recipients who receive tissues later deemed to have been unsuitable for transplantation," it found. Nor were companies required to report errors "or to report adverse events associated with the transplantation of human tissue."

Following a series of stories published in 2000 by California's *Orange County Register* about problems and profits in the tissue industry, the Office of Inspector General for Health and Human Services found nothing had changed. "There is no national system for tracking the availability of tissue," the 2001 report read.

That year U.S. lawmakers convened a hearing. They wanted to know why the government couldn't properly regulate the rapidly-changing industry.



At Queen Astrid Military Hospital in Brussels, tissue products are stored in nitrogen until needed. Photo: Mar Cabra

“We do not even know where the tissue goes right now. There is not even a way to sort out and track what happens to the tissue,” George Grob, then-deputy inspector general for the U.S. Department of Health and Human Services, told lawmakers. “And with the modern tissue banking industry, there are so many new processes coming into play all the time that it is difficult to even

define the stages through which the tissue is going.”

In 2005, the FDA implemented rules requiring tissue banks to track their tissues from donor to distributor. But banks and hospitals maintained different tracking systems. And the government verified compliance through sporadic on-site inspections. Only about 40 percent of banks in operation today have any

associated federal inspection record, according to an ICIJ analysis of the FDA's inspection data.

Companies were also required to report at least the worst adverse events — but the company was given broad discretion to draw the final determination. For example, between September 2010 and October 2011, RTI received 758 complaints or reports of adverse reaction to their tissue, FDA inspectors noted in the company's 2011 inspection. During that time RTI reported four adverse events to the FDA. The company declined requests for comment.

The AATB refused repeated requests over four months for on-record interviews. But during a background interview representatives said most often an infection following transplant cannot be directly linked to the tissue graft used. "A tiny, tiny, tiny minority when there is an infection ascribed to a specific graft," an AATB official said. "Tissue is safe. It's incredibly safe."

In 2007, the FDA, CDC and United Network for Organ Sharing implemented a pilot traceability system with a clunky name — the Transplant Transmission Sentinel Network. Companies volunteered to take part in the three-year barcode-based program.

The model was a success insofar as products could be tracked efficiently. But the effort also highlighted gaps in the reporting requirements, a lack of understanding the risks of disease transmission, and a lack of coordination among stakeholders.

"Concerns were also voiced about possible liability, impacting the willingness of participants to report adverse events," researchers later noted. "The prototype proved that a system can be built, but to be quickly implemented nationally will require impetus from legislation or regulation."

The program wasn't renewed at the end of its three-year lifespan. The CDC's Kuehnert is optimistic, but the outlook isn't good.

"All I can say is that we recommend it. But there has to be the momentum to make it happen," the CDC's Kuehnert told ICIJ. "I think we take it for granted that cereal you buy at the store has a barcode on it and it can be tracked back if there is some sort of a problem. You can't do that with tissue right now." ■

Contributors to this story: Vlad Lavrov, Martina Keller and Michael Hudson



Mandi Eisenbeis and her mother Patricia Towle. Photo: Dan Evans

Abusing the ‘Gift’ of Tissue Donation

By Kate Willson

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MANDI EISENBEIS stood over her dad. It was a Thursday in May 2011 when she said her private good-byes at a funeral parlor in Lodi, Calif. George “Randy” Eisenbeis had died young, felled at age 57 by a methamphetamine overdose.

As she looked at him lying in the coffin, she noticed his hands were oozing blood.

Eisenbeis didn’t know what had happened until later, when she learned the funeral director had sent a scathing complaint to the California Transplant Donor Network, the

The [organ] bank told Mandi Eisenbeis at least four times during the recorded consent process that the body would be properly put back together.

nonprofit organ and tissue bank that had stripped out Randy Eisenbeis' usable parts.

"To say this was simply a 'hack job' would be a compliment," Lodi Funeral Home's Michael Collins wrote in a letter accompanied by a series of graphic photos of the torn-apart corpse. "I guess we should consider ourselves lucky that you left his head and his hands for viewing, and yes, that is his severed foot in the photo to the bottom left of the embalming table."

In March the family sued the California organ bank, accusing it of fraud, mutilation of a corpse, and infliction of emotional distress.

According to call logs made of the consent process, the bank told Mandi Eisenbeis at least four times during the recorded consent process that the body would be properly put back together. She and the family couldn't give informed consent, the lawsuit charges, because those promises were lies designed to manipulate them into giving their okay.

The California Transplant Donor Network is accredited by the industry gold standard — the American Association of Tissue Banks. According to its policies, tissue banks are required to reassemble a body out of respect for donors, their families and the professionals who handle bodies on their way to burial or cremation.

The tissue bank declined requests to comment for this story. In court filings the tissue bank has denied wrongdoing. In an earlier public statement the organization suggested that Randy Eisenbeis' corpse had been in good condition when it sent it to the morgue for autopsy. "No matter how complex the reconstruction process may be, it is a standard to which we adhere consistently," it said. "Unfortunately, we cannot speak to what may transpire once a donor's body leaves our control."

The medical examiner's autopsy findings, however, reported that Randy Eisenbeis came to him naked and skinned, with his feet "separated from the ankles."

What happened to Randy Eisenbeis may not be typical of how bodies are treated when they enter the tissue donation system. But as a worst-case scenario, his story provides a window onto a system that some say operates with inadequate regulatory scrutiny — and raises questions about how well the industry lives up to its own standards about the manner in which tissue banks obtain consent to take tissues from the recently departed.

Families often know little about what happens after they say, “Yes.” Ethics experts say many families in the U.S. and other countries assume that standard donor agreements apply only to hearts, lungs and internal organs. They don’t realize that in the brave new world of tissue harvesting, the dead’s bones, skin, tendons and heart valves can be cut out and used to create medical devices that can be sold for profit around the world.

Lack of Information

Tissue from about 30,000 cadavers in the United States is cleaned and milled into medical devices each year and some is exported around the world. U.S. companies also obtain tissue from places including

Slovakia, the Czech Republic and Latvia.

In many countries, the law allows tissue harvesting unless a donor opts out before death. In the United States, federal law requires that tissue harvesters get families’ approval. How they do that is up to states to decide — and many states have few requirements or guidelines. People are often unaware just what they are giving away when they agree to become a donor. And families often don’t know that when they okay donations to nonprofit organizations such as the California Transplant Donor Network, the tissue routinely goes to for-profit companies, feeding a billion-dollar industry that uses those tissues for everything from repairing a knee to plumping up a penis.

Without uniform federal standards, it is mostly left up to tissue banks to decide how much information to share with donor families. Few states require that companies tell families their loved ones’ tissue can be sold overseas, sent to a for-profit company or used in cosmetic procedures such as wrinkle-fillers and nose jobs.

“At present the industry thrives because of public ignorance and indifference regarding the for-profit

involvement,” Robert Katz, a law professor from Indiana University wrote in 2006. “Most donors are either unaware of such involvement, or it does not trouble them enough to stop donating.”

In a 2010 study by researchers Laura Siminoff and Heather Traino, 70 percent of donor families said they’d object to a loved one’s tissue going to a for-profit business. Yet fewer than one in five said they’d been told that the harvested tissues could go to a for-profit company.

U.S. Sen. Chuck Schumer, a New York Democrat, introduced legislation in 2007 that would have established mandatory requirements for what banks had to tell donor families, as well as try to limit the profits companies can make from the donation. But the bill died after heavy lobbying by the industry, Schumer said.

Industry representatives have declined to answer questions for this story.

A Legal Gray Area

Chris Truitt, a former industry insider, is among the advocates who are working to reform the system and force companies and nonprofits involved in the process to do a better job of informing the grieving about

what will happen to remains of family members who’ve died. Truitt is the author of a book, “The Dark Side of Tissue Donation,” which exposes what he sees as abuses and profiteering within the donation system.

He began working in the industry after living through a family tragedy.

His daughter, Alyssa, was born with a condition that causes fluid to build in the brain. When Alyssa died at age 2, the Truitts donated her organs and tissues. It soothed the pain to know their daughter’s death had helped others in need. He and his wife began promoting donation.

“I felt it was basically my calling in life,” Truitt said. “I ended up doing what I could to find a position working in the field.”

Truitt signed on with nonprofit tissue bank Allograft Resources of Wisconsin. “My job was to go out and do the procedures. To recover bones, skin, veins, heart valves,” he explained. “We’d take the long bones out, we’d take skin out, take the veins out, take the heart valves out.”

The tools were mostly those found in any operating room — scalpels, retractors, scissors, and clamps. Sometimes, though, Truitt and other recovery technicians also used metal wedges and mallets to break through the bone.



Chris Truitt, donor father and former tissue bank worker. Photo: Narayan Mahon

Still, they prided themselves on being “stewards of the gift.” Donors, he said, were treated with respect. Once, an elderly woman whose husband had died thanked Truitt for his work. “She said that at his age in life, he and she both felt that they were completely useless, they had nothing left to give. But by being able to donate, it kind of showed that they still meant something, they were still worth something, they were still able to help somebody.”

But the bank’s record keeping was abysmal, making it impossible to track the tissue from donor to hospital buyer. In 2000 the U.S. Food and Drug Administration issued a warning letter — a serious and uncommon reproach. That’s when RTI Biologics — which had until then bought all the bank’s tissue — took over responsibility for its operations.

Once RTI got more involved in daily operations, Truitt said, training was upgraded. Experts came

“The for-profit trade in body parts is a legal gray area. This affects the confidence of the public and the whole donation process.”

in to show him and his coworkers how to recover tissue in the most efficient manner. “I don’t think they made it any more professional,” he said. “I think they made it more industrial.”

The industrial part of processing and distributing tissue is so different from the soft nonprofit face that donor families are often shocked. “The for-profit trade in body parts is a legal gray area,” said Joshua Slocum, executive director of the Funeral Consumers Alliance. “This affects the confidence of the public and the whole donation process.”

Truitt has nothing against for-profit companies being involved in the industry. He just wants families to be fully informed when the dead’s remains are used to make commercial products. “What I’m saying is that I want that choice. I want to be able to know what that means. And I don’t think that’s what families are getting.”

That can be a challenge, given differences in disclosure laws among states as well as families’

vulnerability during the time of grieving.

Some families don’t want all the details, and it’s up to the organization seeking the tissue to judge how much to disclose, according to Christina Strong, a lawyer for organ and tissue banks and an expert on donation regulations.

Some families, Strong said, might say, “This is freaking abuse. Look, I’m giving OK. That’s it.” Others might say, “Yes, take it,” but they want an open casket funeral, which means that they need to be aware of the kinds of tissues to be taken and how that will affect the person’s appearance and clothing selection.

Most tissue donation center requests analyzed in the 2010 study didn’t tell families that they could decide not to donate. And none told families they could change their minds after initially agreeing, according to the study published earlier this year in *The Journal of Trauma*, a medical journal.

Families often have even less

information and fewer rights when it comes to harvesting tissue from the dead overseas. Express consent isn't required, for example, when a company gets tissue from some former Soviet nations.

RTI's trade-partner turned subsidiary, Tutogen Medical, has obtained tissue from the Czech Republic, Hungary and Latvia, where everyone is a donor unless they expressly opt out. The company also obtains tissue from Ukraine, where government morgues can recover tissue from the dead if they gain family consent.

Four of Tutogen's Ukrainian suppliers have been investigated for allegedly taking tissue against the wishes of donors or their families. The first case was dismissed when prosecutors couldn't prove the tissue had been transplanted. The second was dismissed after the defendant died while a court deliberated his case. Two recent investigations are still pending.

The income that can be made from recovery to distribution is anywhere from \$80,000 to \$200,000, according to industry experts and court testimony. There is a cost involved in recovering, processing and distributing the tissue.

Overseas and in the U.S., some

companies that profit from human tissue spend considerable resources cultivating sources of fresh bodies.

Phillip Guyett, who worked as a ground-level body wrangler in California, North Carolina and Las Vegas before he was sent to prison for falsifying death records, said the demand for tissue grows more intense every year. One tissue buyer, Guyett said, summed up the all-out competition for corpses this way: "Whoever has the most bone wins."

A Profit Machine

When RTI took over the Wisconsin tissue bank where Chris Truitt worked, he said employees were pushed to compete hard with other tissue banks for access to bodies — courting hospitals, funeral homes and morgues. "We would convince them when they came across a death to call us in for the tissue, rather than some other tissue bank," Truitt said.

Once the tissue left the bank, it was sent to RTI, sterilized and milled into implants. "It is a medical device. It's regulated as a medical device," he said. "It's no longer part of Uncle John. It's product XYZ123."

Skin from the Wisconsin bank



A tissue bank performs a tissue recovery.

was also sent to New Jersey-based LifeCell. Truitt says a representative of LifeCell initiated an award for the person who could recover the most tissue from a donor. He said the award was named the Golden Dermatome Award after the instrument designed to strip layers of skin off a donor's back, thighs and arms.

LifeCell did not respond to questions about the award but said in a statement to ICIJ that the company "is committed to improving patients' lives."

"When they started giving out those rewards, it really sunk into me that instead of being stewards of the gift and treating each donor with the ultimate in respect, the company was actually looking at each donor as a profit machine, as nothing more than raw resources," Truitt said. "And it was our job to take as much of those resources as we possibly could."

He left the bank, disillusioned that any profits could be made from recycling human tissues from do-

nors like his daughter. He even had his name removed from his state's list of tissues donors, but remains an organ donor. He hasn't given up hope.

"Saving lives, making lives better. That's what it should be all about," Truitt said. "I talk with a lot of recipients. I talk with a lot of donor families. And we all feel the same thing. It's too important a thing, too incredible a thing to just stop. We have to fix it instead."

Mandi Eisenbeis hopes that her family's lawsuit, filed this spring in San Joaquin County (Calif.) Superior Court against the California Transplant Donor Network, will spur that kind of reform among recovery banks.

The case is still in its early stages; the family's lawyers hope lawmakers will notice the case and call for changes in how they obtain consent and treat donor bodies.

Eisenbeis said the condition of her father in the coffin — and the photos she saw afterward that showed the full picture of the mutilation — roused her to take her complaints to the bank.

Three times, she said, she sent copies of the funeral director's letter and pictures to the tissue bank. Three times the bank said it never



[Video: Skin and Bone](#)

received the mail. Then, she said, it stopped picking up the phone at all.

It was only after getting the silent treatment, she said, that her family decided to file the lawsuit.

"I don't want anyone to go through what I felt the day I saw those pictures," she said. "For me, I just wanted things to change, and when I saw those pictures I knew that I had to do everything I could to get someone to stand up and listen to me." ■

This story was co-reported by National Public Radio (USA).

Contributors to this story: Vlad Lavrov, Martina Keller and Thomas Maier

Methodology: Behind the Numbers

By The International Consortium of Investigative Journalists

ICIJ used four databases provided by the Food and Drug Administration in its analysis of the tissue banking industry. Those databases include the Human Cell and Tissue Establishment Registration, the Operational and Administrative System for Import Support (OASIS), and data sets on tissue bank inspections and deviations. We also analyzed membership of the American Association of Tissue Banks (AATB).

The tissue bank registry was the core dataset used in the analysis. It covered registrations from Jan. 1, 2001 through Feb. 20, 2012. We relied only on the “registered” banks for standard descriptive statistics to compare trends in registration over time. “Pre-registered” entities may also be active but have not been assigned an FDA Establishment Identifier (FEI). Inactive entities no longer included critical data such as tissue types or bank function.

OASIS data covered imports from January 2003 to February

2012. The FDA was unable to provide data on all imports comprising human tissue, as it does not maintain distinct product codes for medical devices containing human tissue. In more than 900,000 import records the FDA indicated could include human tissue, ICIJ could clearly identify only 14,749 containing human tissue.

Inspections covered Jan. 1, 2000 to Feb. 20, 2012, the most recent data available. ICIJ ran descriptive statics on these data to show trends in tissue bank registration since 2001 and inadequacies in FDA oversight — discounting any inspections that occurred prior to initial registration. ICIJ also discounted any inspect data with a “Pre-registered” status, as it was not possible to join to the registration data using the FEI. ICIJ also discounted “inactive” banks in our analysis as the registration data did not provide a date of de-activation. The inspection data included 75 FEIs that did not match on any

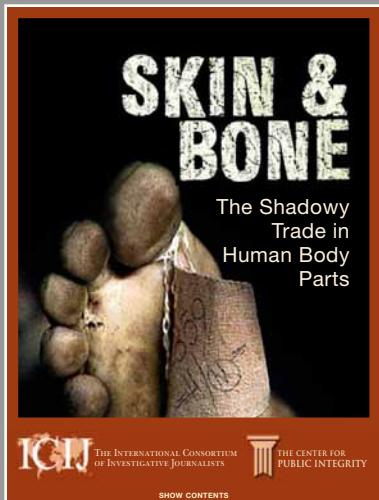
tissue establishment listed in the tissue bank registry — two percent of the total registrations.

Data on deviation reports filed by tissue banks span July 2007 to April 2012. ICIJ used the date of discovery and date of reporting to analyze how many reports were filed within the allowable 45-day window.

For our analysis on tissue banks accredited by the American Association of Tissue Banks, ICIJ relied on the membership list posted on

the AATB website. According to the association, all satellite offices of listed banks also fall under the AATB accreditation. ICIJ manually entered the FEI for each AATB bank and satellite office, then joined it to the tissue bank registry using the FEI available in the registry.

How did we connect the dots and map relationships within the global tissue trading network? Find out how we analyzed the data at: www.icij.org/blog/2012/07/analyzing-data-behind-skin-and-bone ■



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