

# H.R. 1835- The Consensual Donation and Research Integrity Act of 2019

## Background Organ, Tissue and Full Body Donation

Members of the National Funeral Directors Association treat the deceased with the upmost respect and care, help families to honor the life of their loved one and support families regardless of their chosen method of disposition. Many families chose burial or cremation, but funeral directors also help families who make the life-affirming decision to donate their deceased loved one's organs and tissue, or even choose to make a full body donation.

### Deceased Donation

Donate Life America defines deceased donation as "the process of giving an organ or a part of an organ, at the time of the donor's death, for the purpose of transplantation to another person." This procedure usually involves organ (heart, liver, lung kidney, intestines, pancreas); eye (cornea); or tissue donations. When donating organ and tissue, a family can usually specify which organs they wish to donate in advance and can oftentimes still opt for an open-casket funeral.

- The FDA regulates human cells or tissues intended for implantation, transplantation, infusion or transfer into a human recipient.
- The Health Resources and Services Administration, an agency of the U.S. Department of Health and Human Services (HHS), oversees the donation and transplantation of vascular organs, such as hearts, kidneys, and livers.

### Whole Body Donation

Some people choose to donate their body to science. With whole body donation, body parts are not transplanted into other humans, but are instead used for education, research or the advancement of medical, dental or mortuary science. Researchers rely on donated human body parts to develop new surgical instruments, techniques, implants, medicines and treatments for diseases. Surgeons, paramedics and funeral directors use donated bodies and body parts for training, education and research.

In most states, whole body donations may be made to a university, a state agency or a non-transplant tissue bank, which includes brokers who sell the bodies. The brokers make money by providing bodies and dissected parts to companies and institutions that specialize in advancing medicine and other trades through critical training, education and research.

- The poor and elderly are often encouraged to donate their loved one's body to science because some non-transplant tissue banks pick up the body, transport it and cremate it for free.
- Most university and state-run anatomy programs do not actively solicit donations.
- Some medical schools have reported that competition from body brokers has reduced the number of bodies donated to schools to train students because some brokers are able to offer donors more favorable terms, such as free removal of the body.

### Current Regulations

Non-transplant tissue banks are not covered under the same laws that cover organ and tissue transplantation. Few state laws provide any oversight whatsoever and almost anyone, regardless of expertise, can dissect and sell human body parts.

- Under the Uniform Anatomical Gift Act, most state anatomical gift laws largely regulate just one side of the process – how a body may be donated. Most do not address what happens next, such as how brokers dissect, handle and ship the parts; the prices they set on human remains; to whom they sell them; how the parts are used by buyers; or the rights of donors and kin.
- In almost every state, it's legal to sell the human remains of adults.
- Generally, a broker can sell a donated human body for about \$5,000, though prices sometimes top \$10,000.
- Bodies and body parts can be bought, sold and leased, again and again. As a result, it can be difficult to: track what becomes of donors' bodies, ensure that they are handled with dignity and returned to their loved ones after cremation.

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H.R. 1835 was introduced to ensure the consensual donation and respectful disposition of human bodies and non-transplantable human body parts donated for education, research and the advancement of medical, dental and mortuary science for research purposes by amending the Public Health Service Act (42 U.S.C. 301 et seq.).

## Registration

Any person who acquires, transfers or affects interstate commerce using a human body or human body part for education, research, or the advancement of medical, dental, or mortuary science (and not for use in human transplantation) shall register with the Secretary at such time and in such manner as the Secretary (HHS) may require.

- The Secretary shall establish a fee for registration and renewal.
- The Secretary shall determine the amount of the fees authorized on an annual basis based on the projected cost of implementing and enforcing, including the cost of inspections.
- The fees authorized shall be available for obligation only to the extent and in the amounts provided in advance in appropriations Acts.

## Inspection

- The Secretary shall require that the registration be renewed at such intervals as the Secretary determines appropriate.
- The registrant shall notify the Secretary of any change to applicable information in writing not later than 30 days after said change occurs.
- The Secretary shall inspect at regular intervals (to be prescribed by the Secretary) the premises.

## Chain of Custody

A registrant shall compile or maintain a record for each case in which the registrant acquires a human body or human body part, including:

- Documentation that the donor has knowingly consented to the transfer of the human body or human body part.
- Documentation that the donor has been informed of the obligation of the registrant to dispose of the human body or human body part.
- The date and time of the donation or transfer from the donor.
- The name of the person, including any trade or business name, who transferred the human body or human body part to the registrant, if applicable.
- The full name and most recent address of the donor.
- A description of the human body or human body part being acquired or transferred.
- The medical history of the donor, including the autopsy report if an autopsy was conducted.
- The identity and address of each person who has been in possession of the human body or human body part prior to the registrant, including any funeral home, coroner, hospital, organ procurement organization or tissue bank.
- Documentation of the use and disposition of each human body or human body part by the registrant.
- Documentation of the name and address of each person to whom the registrant transfers such human body or human body part.

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## Labeling and Packaging

A registrant shall ensure that all human bodies and human body parts in the possession of, or transferred by, a registrant are labeled and packaged in accordance with applicable laws and shall contain the following:

- The proper name of the donor.
- A description of the contents of the package, indicating whether it is a human body or human body parts, including a list of all such parts.
- The name, address and any applicable license or registration number of the person transferring the human body or human body part.
- The tissue types of the human body or human body part.
- The cause of death of the donor, if applicable and known.
- Serological test results, if any such results exist.
- Any known infectious disease agents of the human body or human body part.
- A statement about the use of personal protective equipment and universal precautions when handling a human body or human body part as required by law.
- The statement 'not for transplantation.'

## Packaging Requirements

Each human body or human body part shall be wrapped and packaged in a manner that:

- Mitigates potential contamination and cross contamination;
- Mitigates potential safety hazards;
- Is sealed to prevent leakage; and
- Ensures the integrity of the human body or human body part.

## Disposition

The registrant shall ensure the proper disposition of a human body or human body part by returning the human body or human body part to a relative or personal representative of the donor or carrying out the disposition in accordance with applicable law.

- If the registrant is transferring the human body or human body part to another person, contracting with such person to assume the obligation in accordance with applicable law.

## Violations

- Any person who violates a requirement of this Act shall be fined in accordance with title 18, United States Code.
- The Secretary may suspend or revoke the registration of any registrant found to be in violation of this Act.

The Consensual Donation and Research Integrity Act of 2019 falls under Energy and Commerce Committee jurisdiction.

For questions about the Consensual Donation and Research Integrity Act of 2019 or to sign on as a co-sponsor, contact Nishith Pandya (Nishith.Pandya@mail.house.gov) in Rep. Bobby Rush's office, or Shayne Woods (Shayne.Woods@mail.house.gov) in Rep. Gus Bilirakis's office.

Just a few examples of body brokers that chose to forego the meticulous quality control procedures and sophisticated training called for by the American Association of Tissue Banks, a national accreditation organization, as reported by Reuters:

Southern Nevada Donor Services offered grieving families a way to eliminate funeral costs: free cremation in exchange for donating a loved one's body to "advance medical studies." In the fall of 2015, neighboring tenants began complaining about a mysterious stench and bloody boxes in a dumpster. Health inspectors learned that Southern Nevada Donor Services was operating as a body broker and upon visiting the facility, found a man in medical scrubs holding a garden hose, thawing a frozen human torso in the midday sun. As the man sprayed the remains, "bits of tissue and blood were washed into the gutters."

In 2018, Detroit body broker Arthur Rathburn was sentenced to nine years in federal prison for selling and renting body parts infected with HIV and hepatitis to unsuspecting buyers at medical and dental schools across the country.

In 2016, Reuters reported that more than 20 bodies donated to an Arizona broker were used in U.S. Army blast experiments – without the consent of the deceased or next of kin. Some donors or their families had explicitly noted an objection to military experiments on consent forms. Family members learned of the 2012 and 2013 experiments, not from the Army but from a Reuters reporter who obtained records about what happened.

In Honolulu, police were called twice to storage facilities leased by body broker Bryan Avery in 2011 and 2012. Both times, they found decomposing human remains and both times, police concluded that Avery committed no crimes because no state law applied.

A woman in New Mexico claimed that employees from Albuquerque broker Bio Care visited her and made a heartfelt pitch: the generous gift of her loved one's body to science would benefit medical students, doctors and researchers, citing several possible contributions, including that her father's body might be used to train surgeons on knee replacement techniques. It took weeks longer than promised to receive what she was told were her father's cremated remains and once she received them, she suspected they were not his ashes because they looked like sand. She was correct. In April 2010, she was told by authorities that her father's head was among body parts discovered at a medical incinerator. She also learned – for the first time, she said – that Bio Care was in the business of selling body parts. Inside Bio Care's warehouse, authorities found at least 127 body parts belonging to 45 people. "All of the bodies appeared to have been dismembered by a coarse cutting instrument, such as a chainsaw," a police detective wrote in an affidavit. Bio Care owner Paul Montano was charged with fraud.