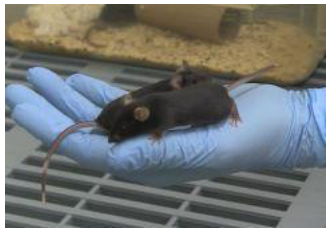
FDA Acquiring 'Fresh' Aborted Baby Parts to Make Mice With Human Immune Systems

By Terence P. Jeffrey (/web/20180807185139/https://www.cnsnews.com/author/terence-p-jeffrey) | August 7, 2018 | 11:48 AM EDT



(NIH Video/Screen Capture)

(CNSNews.com) - The U.S. Food and Drug Administration signed a new contract on July 25 to acquire "fresh" human fetal tissue to transplant into "humanized mice" so that these mice will have a functioning "human immune system," according to information published by the FDA (https://web.archive.org/web/20180807185139/https://cdn.cnsnews.com/attachments/pre-solicitation_notice-fda-06-13-2018.pdf) and the General Services Administration (https://web.archive.org/web/20180807185139/https://www.fpds.gov/ezsearch/search.do?q=advanced+bioscience+resources+VENDOR_DUNS_NUMBER%3A%22786845982%22&s=FPDSNG.COM&templateName=1.4.4&indexName=

"The objective is to acquire Tissue for Humanized Mice," said a June 13 FDA "presolicitation notice" for the contract.

The contractor, the notice said, would "provide the human fetal tissue needed to continue the ongoing research being led by FDA.

“Fresh human tissues are required,” said the notice, “for implantation into severely immune-compromised mice to create chimeric animals that have a human immune system.”

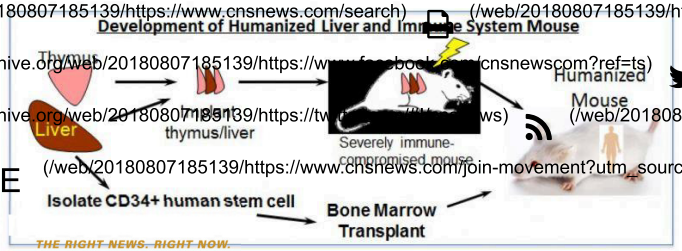
According to GSA’s federal contract database (https://web.archive.org/web/20180807185139/https://www.fpds.gov/ezsearch/search.do?q=advanced+bioscience+resources+VENDOR_DUNS_NUMBER%3A%22786845982%22&s=FPDSNG.COM&templateName=1.4.4&indexName=awardfull), Advanced Bioscience Resources (ABR), a non-profit organization based in the San Francisco Bay Area, was awarded this $15,900 contract, which will run through July 25, 2019.

“Fetal tissue used in research is obtained from elective abortions,” says the Congressional Research Service (https://web.archive.org/web/20180807185139/https://cdn.cnsnews.com/attachments/fetal_tissue_research-frequently_asked_questions-crs-07-31-2015.pdf).

In 2016, Harvard University provided the House Energy and Commerce Committee’s Select Investigative Panel on Infant Lives with a background paper explaining that mice with human immune systems “are engineered to this condition only by means of the use of human fetal material” and that this material can only come from aborted babies not from miscarriages. (See the Harvard backgrounder by clicking here (https://web.archive.org/web/20180807185139/https://www.cnsnews.com/news/article/terence-p-jeffrey/harvard-background-paper-fetal-tissue-research).)

Thus, by issuing a contract to acquire human fetal tissue to use in making mice with human immune systems, the FDA is using federal tax dollars to create a demand for human body parts that must be taken from babies who are aborted.

Because it would not be able to create its “humanized mice” without fresh tissue taken from aborted babies, the FDA also has an interest in the continuation of legalized abortions at a stage in fetal development when the tissue needed to create these mice can be retrieved from the aborted baby.



(https://web.archive.org/web/20180807185139/https://cdn.cnsnews.com/presentationgraphic1.jpg)

The above graphic depicting the creation of a humanized mouse was included in a November 2016 FDA presentation posted on the FDA's websit (https://web.archive.org/web/20180807185139/https://cdn.cnsnews.com/attachments/cder_for_nctr_sab_nov2016_5087.pd

While the FDA confirmed to CNSNews.com that its June 13 presolicitation notice for a contract to “acquire Tissue for Humanized Mice” and the July 25 contract it signed with ABR (as reported on the GSA contract database) refer to the same deal, the FDA declined to answer 17 other questions CNSNews.com asked it about that contract and the aborted baby parts it requires the contractor to provide. (See the full set of questions CNSNews.com sent to the FDA by clicking here (https://web.archive.org/web/20180807185139/https://www.cnsnews.com/news/article/terence-p-jeffrey/questions-sent-fda-and-abr-humanized-mice-contract).)

Instead the FDA provided CNSNews.com with a three-paragraph statement. (See the FDA’s full statement by clicking here (https://web.archive.org/web/20180807185139/https://www.cnsnews.com/news/article/terence-p-jeffrey/questions-sent-fda-and-abr-humanized-mice-contract).)

In its specific questions, CNSNews.com asked the FDA to disclose:

--The total number of babies expected to donate their tissue to the FDA to create humanized mice during the year-long duration of the contract.

--Whether the FDA needed to know that the abortion of a donor baby was taking place so FDA researchers could be prepared to implant this baby's "fresh" tissue into mice in a timely manner.

--What the gestational age of the babies must be to provide the tissue needed to create these "humanized mice."

--Whether there were any methods of abortion that could not be used to terminate the babies whose tissue would be used by the FDA to create humanized mice because that method would cause the tissue to be damaged or spoiled in a way that would make it unsuitable for this research.

The FDA also would not answer this question: "Are the mothers who agree to donate the tissue from their unborn babies for this FDA research informed that tissue taken from their aborted baby will be transplanted into a mouse?"

In its statement to CNSNews.com, the FDA stressed that it was committed to making certain its research followed "all legal requirements" and met "the highest ethical standards."

"The U.S. Food and Drug Administration is committed to ensuring that its research is conducted responsibly, conforms with all legal requirements, and meets the highest ethical standards," said the FDA statement.

"At the FDA, research involving human fetal tissue accounts for a very small fraction of the FDA's total research and has been used in situations where it is critical to understanding how the human immune system responds to certain drugs and biologics," the statement said. "This work has led to a better understanding of a number of conditions and diseases that affect millions of Americans.

"The FDA's researchers obtain fetal tissue from a non-profit Tissue Procurement Organization (TPO) that have [sic] provided assurances that they are in compliance with all applicable legal requirements, including relevant provisions relating to research involving human fetal tissue," said the statement.

"FDA is not involved in the TPO's sourcing of the tissue," it said.

"In addition," the statement continued, "the FDA has in place systems to ensure FDA research using fetal tissue, as well as any research funded by FDA, is in compliance with applicable

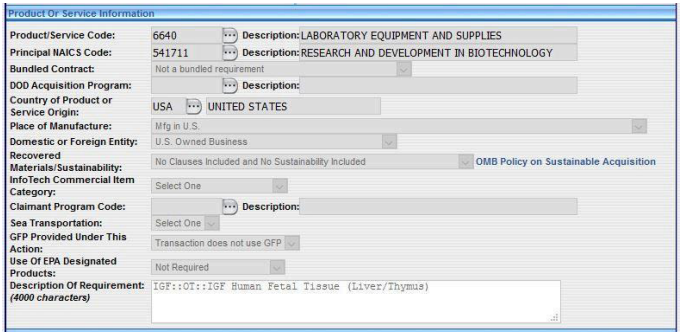
federal, state and local regulations and guidelines, as well as FDA policies."

Since 2012, according to the GSA's Federal Procurement Data System (https://web.archive.org/web/20180807185139/https://www.fpds.gov/ezsearch/search.do?q=advanced+bioscience+resources+VENDOR_DUNS_NUMBER%3A%22786845982%22&s=FPDSNG.COM&templateName=1.4.4&indexName=), the FDA has signed eight contracts with ABR, including the one signed July 25. Seven of these expressly cite "Humanized Mice," "Human Fetal Tissue" or "Tissue Procurement for Humanized Mice" in the contract's "description of requirement." The eighth simply says: "Human Tissue."

The "description of requirement" for the latest contract is only two words long. It says: "Humanized Mice."

The FDA's most recent prior contract with ABR ran from July 13, 2017 to July 12, 2018. It carried this description: "Tissue Procurement for Humanized Mice—other functions."

Before that, the FDA had a contract with ABR that ran from May 10, 2016 to May 15, 2017. Its description of requirement said: "Human Fetal Tissue (Liver/Thymus)."


Product Or Service Information

Product/Service Code:	6640	Description: LABORATORY EQUIPMENT AND SUPPLIES
Principal NAICS Code:	541711	Description: RESEARCH AND DEVELOPMENT IN BIOTECHNOLOGY
Bundled Contract:	Not a bundled requirement	
DOD Acquisition Program:		Description:
Country of Product or Service Origin:	USA	UNITED STATES
Place of Manufacture:	Mfg in U.S.	
Domestic or Foreign Entity:	U.S. Owned Business	
Recovered Materials/Sustainability:	No Clauses Included and No Sustainability Included	OMB Policy on Sustainable Acquisition
InfoTech Commercial Item Category:	Select One	
Claimant Program Code:		Description:
Sea Transportation:	Select One	
GFP Provided Under This Action:	Transaction does not use GFP	
Use Of EPA Designated Products:	Not Required	
Description Of Requirement: (4000 characters)	IGF::OT::IGF Human Fetal Tissue (Liver/Thymus)	

(https://web.archive.org/web/20180807185139/https://cdn.cnsnews.com/descriptionofrequirement-05-10-2016.jpg)

This screen capture from the GSA database listing of the contract that the FDA signed with ABR on May 10, 2016 has as the description of requirement "Human Fetal Tissue (Liver/Thymus)"

The FDA's June 13 presolicitation notice contended that Advanced Biosciences Resources was the only organization that could fulfill the new contract.

"ABR is the only company in the U.S. capable of supplying tissue suitable for HM research. No other company or organization is capable of fulfilling the need," the FDA notice said.

"The government intends to solicit and negotiate directly with Advanced Bioscience Resources (ABR) Inc., and no solicitation will be issued," it said.

"The objective is to acquire Tissue for Humanized Mice," it said.

"ABR is the only company that can provide the human fetal tissue needed to continue the ongoing research being led by the FDA," said this FDA notice. "Fresh human tissues are required for implantation into severely combined immune-compromised mice to create chimeric animals that have a human immune system. This human immune system allows us to test biological drug products for safety and efficacy. This is necessary because these drug products do not bind non-human species drug targets."

CNSNews.com sent ABR the same set of questions it asked the FDA. However, ABR did not respond.

In investigative reports published in December 2016, the Senate Judiciary Committee (https://web.archive.org/web/20180807185139/https://cdn.cnsnews.com/attachments/2016-12-13_majority_report_-_human_fetal_tissue_research_-_context_and_controversy4.pdf) and the House Energy and Commerce Committee's Select Investigative Panel on Infant Lives (https://web.archive.org/web/20180807185139/https://energycommerce.house.gov/news/letter/select-investigative-panel-final-report/) discussed ABR's actions in providing researchers with human fetal tissue retrieved from aborted babies. These actions included having ABR technicians working inside abortion clinics operated by Planned Parenthood affiliates.

"Advance Bioscience Resources, Inc. (ABR) describes itself as 'a non-profit corporate foundation established in 1989 under California law to provide biomedical researchers with access to human tissues," said the Judiciary Committee report. "ABR 'specializes in the procurement, preservation, and distribution of both human fetal tissue and full umbilical cord blood for research."

"For the period covering 2005 to the present, ABR informed the committee that it obtained fetal tissue from two Planned Parenthood affiliates, as well as from seven other independent clinics," said the committee report.

"ABR technicians working at the Planned Parenthood clinics obtain the fetuses from the Planned Parenthood staff and then harvest and immediately ship the fetal tissue specimens," said the report. "The fetal tissue is never stored or otherwise in the possession of ABR."

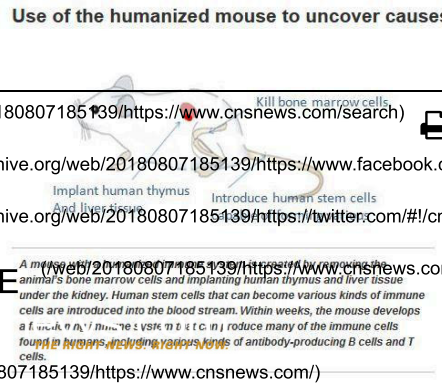
"As ABR's attorneys stated," the report said, "'For purposes of actual procurement, ABR's employees primarily work at a counter in each affiliate's laboratory and are able to access various instruments and supplies from the assigned cabinets and/or refrigerators in the lab, or from the basement. ABR personnel may also access common areas as well as the recovery room to draw blood, as necessary.'"

The FDA has published materials on its website and in a scientific journal indicating that it uses human thymus and liver to create its "humanized mice."

For example, a group of scientists from the FDA's Division of Applied Regulatory Science (DARS) published an article in Therapeutic Innovation & Regulatory Science on July 21, 2017 (https://web.archive.org/web/20180807185139/http://journals.sagepub.com/doi/full/10.1177/2168479017720249) that discussed the FDA's use of humanized mice engrafted with human immune systems like the mice described in the FDA's contract notice.

A graphic in this article—"Making a Mouse with a Human Immune System"—shows how a "severely immune-compromised mouse" is implanted with "human thymus and liver tissue" and injected with "human stem cells" derived from a human liver to create "a mouse with a 'humanized' immune system."

The FDA published a similar graphic in an internal presentation made in November 2016 that included a section on the FDA's use of "Humanized Mouse Models." Yet another similar, if simpler, graphic is posted on the FDA's website.



(https://web.archive.org/web/20180807185139/https://cdn.cnsnews.com/humanizedmousegraphic2.jpg)

This graphic of a humanized mouse is posted on the FDA's website (https://web.archive.org/web/20180807185139/https://www.fda.gov/drugs/scienceresearch/ucm294603.htm).

As previously reported by CNSNews.com (https://web.archive.org/web/20180807185139/https://www.cnsnews.com/news/article/terence-p-jeffrey/us-government-made-humanized-mice-tissue-babies-17-22-weeks), government researchers working for the National Institutes of Health created similar "humanized mice" using livers and thymuses taken from babies aborted at 17 to 22 weeks gestational age.

These NIH researchers published an article in the Journal of Immunological Methods (https://web.archive.org/web/20180807185139/https://cdn.cnsnews.com/attachments/journal_of_immunological_methods-05-2014.pdf) that indicated that Advanced Bioscience Resources—the FDA's fetal tissue contractor—had provided them with the livers and thymuses they needed to make their humanized mice.

The NIH scientists said in this journal article that they "routinely produced cohorts of approximately 40" humanized mice "from a single tissue donor"—n.b. a single aborted baby.

At a Sept. 24, 2007 workshop sponsored by the NIH—"The New Humanized Rodent Model Workshop (https://web.archive.org/web/20180807185139/https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2276217/)"—a federally funded scientist described a type of humanized mouse given a human immune system by implanting it with "human fetal liver and thymus" taken from babies who were 20 to 24

weeks gestational age. The federally funded scientist indicated at this NIH workshop: "A single donor provides sufficient tissue to implant 50–60 mice."

In fiscal 2018, the NIH—which is a separate entity from the FDA but also a part of the Department of Health and Human Services--estimates it will spend $103 million on human fetal tissue research (https://web.archive.org/web/20180807185139/https://report.nih.gov/categorical_spending.aspx). In fiscal 2017, it spent $98 million.

On Sept. 14, 2017, the House of Representatives passed an omnibus appropriations bill that included language pushed by Rep. Martha Roby (R.-Ala.) and other pro-life House members that would have prohibited federal funding of research that uses tissue from aborted babies. This language, however, was not included in any of the spending bills that ultimately passed the Senate and were signed into law for fiscal 2018.

In July, the House Appropriations Committee approved a bill (https://web.archive.org/web/20180807185139/https://cdn.cnsnews.com/attachments/bills-115-sc-ap-fy2019-laborhhs-laborbill.pdf) to fund the Department of Health and Human Services for fiscal 2019. That bill—like last year's version--includes language that prohibits federal funding of research that uses human fetal tissue obtained through an abortion.

For that language to become law, however, it would need to be included in a funding bill that is passed by both the House and Senate and signed by President Donald Trump.

Attachment:

pre-solicitation_notice-fda-06-13-2018.pdf (https://web.archive.org/web/20180807185139/https://cdn.cnsnews.com/attachments/pre-solicitation_notice-fda-06-13-2018.pdf)

fetal_tissue_research-frequently_asked_questions-crs-07-31-2015.pdf (https://web.archive.org/web/20180807185139/https://cdn.cnsnews.com/attachments/fetal_tissue_research-frequently_asked_questions-crs-07-31-2015.pdf)

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2016-12-13_majority_report_-_human_fetal_tissue_research_-_context_and_controversy4.pdf (https://web.archive.org/web/20180807185139/https://cdn.cnsnews.com/attachments/2016-12-13_majority_report_-_human_fetal_tissue_research_-_context_and_controversy4.pdf)

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bills-115-sc-ap-fy2019-laborhhs-laborbill.pdf (https://web.archive.org/web/20180807185139/https://cdn.cnsnews.com/attachments/bills-115-sc-ap-fy2019-laborhhs-

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