File fetal tissue.

FETAL TISSUE RESEARCH AND CHOICE

The donation of fetal tissue for research is a legal and ethical practice. Profiteering is illegal.

- The NIH Revitalization Act of 1993 provides that "[I]t shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration..." Under this law, selling fetal tissue is a federal crime punishable by fines, imprisonment for up to ten years, or both. Similarly, the National Organ Transplant Act makes it unlawful for a person "to knowingly acquire, receive, or otherwise transfer any human organ," including fetal tissue, "for valuable consideration…" This law also permits the reimbursement for certain expenses related to fetal tissue donation (transportation, storage, preservation, etc.), just as it does for organ donation.

- Aborted tissue would be discarded if it were not donated, and legal guidelines require that a woman's decision to terminate a pregnancy is made first – and totally separately – from that of whether to donate tissue.

- When asked to review the appropriateness of research using fetal tissue, a National Institutes of Health panel recommended allowing such research, as long as sufficient protections for women and against conflicts of interest were enacted. (Their recommendations were written into the federal law that now governs research with fetal tissue.) The Institute of Medicine and National Academy of Sciences have also examined the issue and concluded similarly.

- Even those who may oppose abortion in the strongest possible way should support fetal tissue research. As bioethicist John Robertson argues: "In sum, fetal tissue transplants are practically and morally separate from decisions to end unwanted pregnancy." Further, Robertson says, "The disparate issues … can be treated separately, so that ethical concerns and the politics of abortion do not impede the progress of important research."

Research using fetal tissue is an important component of medical science.

- Due to their capacity to divide rapidly, grow, and adapt to new environments, fetal cells hold unique promise for medical research. Research using fetal tissue has yielded significant advancements in the treatment of numerous diseases and medical conditions, including the development of polio and rubella vaccines. Research with fetal tissue promises to help treat many conditions such as spinal cord injury, cancer, Parkinson's disease, diabetes, multiple

sclerosis, birth defects, sickle cell anemia, leukemia, AIDS, Alzheimer's, Huntington's, stroke, degenerative eye conditions, radiation poisoning, and others.

Federal law ensures that a woman's decision to donate is made freely, with proper information, and free from conflicts of interest.

- Federal law not only prohibits the sale of fetal tissue for profit, it also provides that:
  - the physician certify that the woman consented to have the abortion before consenting to donate the fetal tissue, ensuring the two decisions are made independently;
  - the woman certify that she donated the tissue without restriction and without knowledge of the identity of any transplant recipient;
  - no inducements – financial or otherwise – offered to terminate a pregnancy for purposes of research;
  - the woman be informed of any known medical risks associated with tissue donation;
  - the physician disclose any interest (s)he may have in the research to be conducted with the tissue;
  - the physician does not alter an abortion procedure in order to facilitate fetal tissue donation; and
  - the researcher receiving fetal tissue must certify (s)he had no part in any decisions regarding the timing, method, or procedures used for the abortion.

- Federal and state laws regarding fetal tissue donation have as their primary concerns the protection of women and assurance of humanitarian goals.

Attacking fetal tissue donations is the newest tactic in the overall strategy of demonizing abortion.

- If individual cases of wrongdoing are discovered, they should be investigated and prosecuted.

- The fact that Life Dynamics, a fringe anti-choice group, publicized its allegations to politicians and the media – and did not refer them directly to law-enforcement authorities - exposes their true intentions of using these charges to inflame the abortion debate.

- One goal of those opposed to both abortion and medical research is the full disclosure of all confidential information to the government - including the names, addresses, and telephone numbers, of every individual and organization in the chain of fetal tissue possession - *thus exposing each to anti-choice harassment and violence*. Affected entities could be research universities, pharmaceutical companies, biotechnology firms, hospitals, doctors, other medical personnel, and women themselves.

- A common tactic among anti-choice groups is to sensationalize the abortion debate and demonize doctors who perform abortions through the use of incendiary rhetoric. Doctors who perform abortions are just that – doctors. They are bound by the same laws and medical ethical standards as are all other medical professionals. Like other physicians, they work hard every day to provide quality health care services to their patients. Abortion is a legal, private medical decision that should be made by women in consultation with their medical caregivers, not by the government or politicians.

To: Reproductive Health Staff
From: Allison Herwitt, Director of Government Relations
Donna Crane, Legislative Representative
Date: March 6, 2000
Subject: ***Upcoming Hearing on Alleged Profiteering from Research Using Fetal Tissue***

On Thursday, March 9, the House Commerce Subcommittee on Health and the Environment will hold a hearing on the procurement of fetal tissue for research. The hearing is expected to air the allegation that some third-party fetal tissue procurement businesses are making a profit from their transactions. As the committee wades into these allegations, we expect some anti-choice lawmakers and activists – led by the anti-choice group Life Dynamics – also to make allegations that physicians are altering abortion procedures in order to obtain intact fetuses for donation to research. The ABC television program *20/20* is also scheduled to air a segment that includes allegations of illegal profiteering from fetal-tissue donation the evening before, March 8.

These practices, if true, are illegal, deplorable, and violate medical ethics. However, they are being raised in a political arena to sensationalize the debate about abortion in order to serve the larger agenda of curbing women's reproductive freedoms. **While the issues of reproductive choice and fetal tissue donation are – and should remain – separate, anti-choice members will be using these allegations to attack a woman's right to choose abortion.**

Following are key points concerning the relationship between elective abortions and the donation of fetal tissue to research:

- The donation of fetal tissue for research is a legal and ethical practice. Federal law allows a woman to donate aborted fetal tissue, which would be discarded otherwise, for scientific use, and sets out detailed guidelines to ensure that her decision is made freely, with proper information, and is free from conflicts of interest.

- The alleged profiteering to be aired during the hearing is illegal under federal law and punishable by fines, imprisonment, or both. If individual cases of wrongdoing are discovered, they should be investigated and prosecuted. Research using fetal tissue is important for advancing medical research and should not be jeopardized by unsubstantiated

gag rule → Title X
20/20 → bad → DOJ
→ even story?
Thursday → Commerce
→ more of flat fee → administrative fee

BIOTECHNOLOGY The Fetal-Tissue Frontier

By Neil Munro, National Journal
Friday, Feb. 25, 2000

→ Devorah

The attraction of using aborted fetal tissue for research has always been its promise of medical breakthroughs. Activists for patients suffering from Parkinson's disease hope that fetal-tissue research can help find a cure for that affliction. So, too, do groups trying to combat diabetes, Alzheimer's, cancer, AIDS, and a variety of rare ailments.

"I am going downhill ... and I would like to have a fetal-tissue transplant," said former Sen. Brock Adams, D-Wash., a Parkinson's sufferer.

Indeed, in the seven years since Congress authorized the use of fetal tissue for research, there have been some promising developments. Researchers, for example, can add single human genes -- often from fetuses -- to laboratory mice, which have many genetic similarities to humans. In one instance, Dr. Robert Freedman, a researcher at the University of Colorado, grafted onto mice a human gene that he suspects is related to adult schizophrenia. Ten varieties of mice were created and will be studied over several years.

But along with the promise of fetal-tissue research, there are uncomfortable realities. Medical researchers don't just order "fetal tissue" from providers -- they order arm bones, leg bones, livers, spleens, whole eyes, and other organs. And, despite a congressional prohibition against a money-making marketplace for fetal tissue, there are indications that just such a marketplace has developed – that companies are selling fetal parts for a profit.

Anti-abortion groups have gathered price lists and detailed order forms for fetal body parts that they say show extensive lawbreaking and unethical behavior. The documents have attracted notice in Congress. The House Commerce Committee, chaired by Rep. Tom Bliley, R-Va., a longtime opponent of fetal-tissue research, is expected to hold hearings on the subject in March. Sen. Bob Smith, R-N.H., another staunch anti-abortion legislator, also plans to hold hearings soon.

Republicans are torn between two constituencies -- the high-tech research companies that oppose research restrictions, and the social conservatives who are keen to stigmatize abortion and abortion-related research. Abortion-rights groups oppose any new restrictions. Given this incendiary mix, it is not surprising that many legislators won't want to deal with fetal-tissue research, said Adams, who championed the 1993 law. Many legislators, he said, "are going to be in the middle of a debate that they don't want to be in the middle of."

According to Suzanne Rini, the author of a 1988 book, Beyond Abortion: A Chronicle of Fetal Experimentation, the 1993 law is riddled with loopholes and ambiguities that reflect deep national divisions over abortion and abortion-facilitated research: Lawmakers remain deeply divided over the politics of abortion; academic scientists, for-profit companies, and government health-research agencies oppose any restrictions; and patients suffering from incurable diseases desperately want near-miraculous cures as soon as possible.

N.I.H → ? counsel's → Life Dynamics
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Little information is available about how much tissue is collected and exchanged, partly because there are so many collectors and researchers. In November 1993, however, James Bardsley of the Anatomic Gift Foundation, a tissue reseller, told the New York Times that the firm shipped 300 to 600 specimens a month. Opening Lines, another tissue reseller, says in its 1999 sales catalog that its "daily average case volume exceeds 1,500."

No government data are available on the number of tissue brokers, or their practices, revenues, prices, or customers. Moreover, many researchers contract directly with abortion clinics for tissue. Since 1991, the National Institutes of Health has spent more than $150 million on hundreds of fetal-tissue-research programs. The money has funded 230 fetal-tissue-transplant experiments since 1991, and 288 experiments in 1997 and 1998 alone.

Public Law 103-43, the National Institutes of Health Revitalization Act of 1993, governs the sale of fetal tissue. Congress passed the legislation after several years of fierce debate, which reached its peak in 1992 when President Bush vetoed the NIH reauthorization bill. The next year, President Clinton, on his first day in office, signed an executive order that ended federal curbs on fetal-tissue research, and soon thereafter approved the revived NIH bill that boosted federal funding for fetal-tissue research. The law, passed by a large majority, sought to spur federal and private-sector research while simultaneously regulating it.

Some sections of the law are widely supported. For example, section 498B bars the collection of fetal organs from an identified person or their donation to a specific individual, such as a relative. Researchers say this rule has successfully prevented women from conceiving fetuses to serve as organ banks and kept rich patients from buying organs from poor donors.

During the congressional debates in 1992 and 1993, supporters of fetal-tissue research argued that the ethics provisions in the bill would curb the emergence of a marketplace for fetal body parts. "The idea of such a market is barbaric," said Sen. John McCain, R-Ariz., in a May 1992 letter to constituents in which he announced that because of the ethical safeguards added to the law, he had dropped his opposition to fetal-organ research.

"It would be abhorrent to allow the sale of fetal tissue and a market to be established for that sale," said Rep. Henry A. Waxman, D-Calif., a leading abortion-rights advocate.

But Douglas Johnson, legislative director of the National Right to Life Committee, sees the 1993 law on fetal tissue as an attempt "to enshrine language that would not impede the practices but would provide a modicum of cover for legislators who voted for abortion-dependent research. It is a fig leaf."

The current controversy over the sale of fetal tissue and parts focuses on section 498B(a), which declares flatly that "it shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration." Violation of this law can bring a prison sentence of 10 years. But the ban is greatly weakened by clause 498B(d.3), which says, "The term 'valuable consideration' does not include reasonable payments associated with

the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue."

Selling Fetal Parts The question Congress will face first is whether researchers and their suppliers have violated the 1993 law's payment rule. In documents obtained by an anti-abortion group, Life Dynamics, in Denton, Texas, medical researchers don't mince words when placing orders from abortion clinics:

"Arm bones (humeri) must accompany the leg bones (femurs and tibias)," says an order for three to five bones, plus livers, spleens, and thymuses from fetuses older than 18 weeks. The order came from SyStemix Inc., a Palo Alto, Calif., subsidiary of Novartis of Switzerland. The order forms also include many requests from universities, including a request for "whole eyes, 13-20 weeks, 1-2 per donor, fresh" from the Tulane University School of Medicine, which was researching eye surgery.

The price list offered by tissue broker Opening Lines, in West Frankfort, Ill., was similarly straightforward: "Brain [younger than] 8 weeks 30% discount if significantly fragmented $999 ... Eyes [older than] 8 weeks 40% discount for single eye $50. ... Prices in effect through December 31 1999." Anatomic Gift Foundation, in Laurel, Md., charged a flat fee of $90 for every organ or slice of tissue taken during a second-trimester abortion, or $220 for those taken from a fetus 6 weeks to 12 weeks old.

In general, the order forms are perfectly legal. Critics, however, maintain that the price lists show that the tissue resellers are making a profit in violation of the law's "reasonable payments" rule. Alan G. Fantel, who runs an NIH-funded service that supplies free fetal tissue and organs to universities, is especially concerned about the price lists from Opening Lines. "The fact that they are pricing [organs] at different levels leads one to think they are after profit," he said. Miles Jones, the founder of Opening Lines, declined to comment.

Critics of fetal research also charge that the order forms show that demand for fetal tissue has prompted unethical behavior by researchers and abortion clinics. But the law is complicated. Any change to abortion procedures to get more tissue is entirely legal for commercial research, but is largely banned for government-funded research. Under the 1993 law, NIH-funded researchers can use fetal tissue only if the woman's "attending physician ... makes a statement, made in writing and signed by the physician that ... no alteration of the timing, method, or procedure used to terminate the pregnancy was made solely for the purpose of obtaining the tissue." Many universities that receive government money for medical research have voluntarily agreed that all of their researchers -- even those working with outside companies -- will comply with these rules.

Mark Crutcher, the president of Life Dynamics and an abortion opponent, says that abortion providers change their operating-room techniques to maximize tissue collection and profit, thus endangering the patient. For example, Crutcher said, some of the order forms ask that abortion clinics not use standard poisons frequently given to fetuses before abortions; in particular, SyStemix's order form asks for second-trimester legs, arms, livers, and spleens to be removed,

dissected, and stored on crushed ice "within a maximum of ten (10) minutes after circulation has stopped." Crutcher argues that there's no way to do a second-trimester abortion within 10 minutes unless the procedure is changed to delay the death of the fetus.

One way to delay the death of the fetus is to perform a "partial-birth abortion," which is also called "intact dilation and extraction." According to Brent Bardsley of the Anatomic Gift Foundation, which for several years supplied tissue to researchers, including government-funded ones, some clinics use that technique and a low-pressure vacuum for first-trimester fetuses. The vacuum technique is especially important for research into Parkinson's disease, he said, because "they had to have that brain nearly intact ... [and with the normal abortion method] it's nearly impossible." However, said Bardsley, "we strive not to influence the procedure or the patient's decision to have an abortion. We don't need to; there's plenty of material out there."

Changes in abortion procedure, and especially the use of "intact dilation and extraction," are unethical because they pose greater risks to the woman, argued Dr. Gerard Rafferty, an obstetrician at St. George's Hospital in London, who has performed abortions. "Almost nobody does the [intact] D&E in Europe because they are incredibly barbaric and quite dangerous to the mother," he said. Abortion-rights groups disagree, saying the procedure can be safer than its alternatives.

The law's wording complicates this legal issue because it bars modifications to abortions done "solely for the purpose of obtaining the tissue." During the 1993 debate, Bliley sought to strike the word solely, but Waxman argued successfully that it should be preserved so abortions could be modified for "medically necessary reasons." Crutcher and other critics argue that this allows abortion clinics to use tissue-producing techniques while claiming they are necessary for medical reasons.

Benefits To Science Activists for patients suffering from Parkinson's disease are influential in Congress and provided much of the support for the 1993 law. Other groups also campaign for fetal-tissue research. These patients' rights groups have plenty of supporters in Congress, partly because older legislators see their families or legislative colleagues struck ill.

For such patients, the controversial work of Dr. Curt Freed at the University of Colorado offers some hope. Freed has used $5 million of NIH money in a four-year experiment on Parkinson's patients in which he implanted tissue from the brains of seven- or eight-week-old fetuses into 19 patients. The particular piece of brain is the ventral mesacephelon, which contains all the cells that produce a chemical called dopamine. The dopamine-producing cells are intended to offset the loss of dopamine production that causes Parkinson's.

Thus far, Freed's work has yielded few results. Last May, the British medical journal The Lancet reported that "there was no significant difference" between the 19 patients given the fetal transplants and the 20 patients given a placebo operation, although some improvements were noted in patients under 60.

Gillian Woollett, an associate vice president for biotechnology at the Pharmaceutical Research and Manufacturers of America, cautioned against false hopes. Patients' groups "can be part of

overselling," Woollett said, adding that cures may not be forthcoming for many years or decades. Their optimistic prediction of progress "is a psychological thing. I don't think it is realistic."

The defense of fetal-tissue research does not rest solely on the benefits of transplanting the tissue. Scientists are quick to point out that the research has already yielded improved knowledge in the laboratory. For example, research with mice shows that single human genes can be added to that animal. These modified mice, called SCID-mice, then multiply by natural means. In Freedman's research at the University of Colorado, a human gene that may be related to adult schizophrenia has been grafted onto mice. The suspect gene was extracted from two fetuses removed from two Swedish schizophrenia patients after the Swedish abortion team decided the patients were competent to make the decision. A medical therapy resulting from this research is still "decades away," Freedman said. "We don't even understand what is going on in the mice yet."

Fetal organs and tissue are also needed to extend and verify the data being gathered about the human genome, which is the set of instructions within each cell that dictates how human tissue works. As researchers learn more about the myriad genes that tend to make people smarter, sicker, faster, forgetful, beautiful, or bald, they will need to test their theories on human tissue -- especially because the tissue can show how genes interact with one another, researchers say. "If we don't have fetal tissue to do it with, we'll never be able to do it," said Fantel, who runs the NIH-funded service that supplies free fetal tissue and organs to universities.

Fetal-tissue research is especially important, Freedman and other scientists say, because human embryos and fetuses contain special cells -- called stem cells -- that are particularly vigorous and that, when implanted in other people and in animals, are less likely to be rejected by the host's disease-fighting cells. Stem cells might also evolve into many different types of cells, including blood, bone, and brain cells. These stem cells are easiest to find in human embryos, but are increasingly being found in adults. This development creates the possibility that a patient's own cells could be activated to repair problems, such as paralysis, cancer, or Alzheimer's. By studying fetal stem cells, researchers hope to find and fix the root cause of later human diseases, including the mechanisms that trigger uncontrollable cancerous growth or cause adult schizophrenia, Freedman said.

The fetal-tissue and stem-cell work are the building blocks of gene therapy, which researchers say can modify an adult's genes to defeat a disease, repair a disorder, or just to gain an upgrade. But the gene-therapy-research community faces increasing scrutiny following the death last fall of 18-year-old Jesse Gelsinger during a gene-therapy experiment at the University of Pennsylvania.

At an NIH meeting in late December, attendees said that university researchers and companies disregarded risks to patients' health, concealed problems, and exaggerated the promise of research, all in the hope of generating profits in the hot market for new medical products. In mid-January, the Food and Drug Administration shut down all human-subject research experiments under way at the University of Pennsylvania. It said that researchers had recruited 18 patients for the Gelsinger study without checking whether they were eligible, and had failed to inform half of the patients about the known risks.

In late January, NIH officials released data showing that gene-therapy researchers had concealed three deaths and 652 "serious adverse events" from oversight officials. In February, two patients' groups and a Harvard-affiliated medical center announced they were stopping gene-therapy projects. "It is a multisystem failure. ... We may have just touched the tip of the iceberg," said Sen. Bill Frist, R-Tenn., at a Feb. 2 hearing.

In recent months, concern over researchers' priorities has caused officials on the White House-appointed National Bioethics Advisory Commission to consider seeking greater oversight over experiments on humans.

Science Meets Politics At the moment, the main dispute between researchers and anti-abortion groups is over stem cells. Anti-abortion groups want NIH to promote research into adult stem cells, but in late 1999, NIH approved federal funding for research into stem cells taken from human embryos. The agency acted despite the fiscal 2000 Consolidated Appropriations Act, which bars all funding for "research in which a human embryo or embryos are destroyed." NIH officials say that the ban applies only to the use of funds for the act of destroying the embryos.

In the stem-cell debate, as in the broader fight over fetal-tissue research, anti-abortion advocates argue that scientists' interest in fetal tissue is not merely scientific, but is driven by a mix of interests associated with the tissue, including medical value, marketplace competition, low prices, easy availability, and legal advantages. Full ownership of fetal tissue is transferred during donation and leaves researchers with no reason to fear a later lawsuit when the tissue helps produce a billion-dollar blockbuster drug.

Helen Alvare, the director of planning and information for the secretariat for anti-abortion activities at the National Conference of Catholic Bishops, says fetal-tissue research raises "the entire specter of humans being seen as means and not as ends in themselves." The abortion-dependent research is a "huge, steep slope that pushes us onwards to a complete stripping from the human person of the dignity and respect that comes inherently as part of human life ... [and which explains] why humans are different from animals and trees."

Aside from urging NIH funding for alternatives to abortion-related research, critics of fetal-tissue research have not said what legislative remedies should be adopted. Possible legislative solutions, said Sen. Smith, include the mandatory reporting of related data to the Justice Department, the publication of the names of universities and companies that use the tissue, or even a ban on any fetal-tissue exchange. Also, Smith said that publishing the names of researchers would push them to develop alternative research tools, or to rely more on tissue already stored by commercial vendors in tissue banks. He added that he would like to ban fetal-tissue research because a ban would lessen the number of abortions. In a 1995 survey conducted in Canada by the Joint Center for Bioethics at the University of Toronto, 17 percent of 122 abortion-rights supporters said they would be more likely to have an abortion if they could donate the tissue.
Smith said that legislative options must wait until after the hearings he plans to hold in March. But he faces an uphill struggle. Smith narrowly lost an October Senate vote, 46-51, seeking more federal oversight -- but no ban -- of the exchange of fetal body parts. That vote was "a shot

across the bow," said Daniel Perry, the executive director of the Alliance for Aging Research, a coalition of patients' groups and companies that oppose fetal-research curbs. "We will fight like the dickens to ensure this research is not halted ... [restrictions are] a frontal assault on the way we do scientific research." In any public debate, he predicted, the combined weight of patients' groups and researchers will be enough to forestall curbs.

In past fights over fetal tissue, the research community has enjoyed broad support from liberal Republicans, such as Sens. James M. Jeffords, R-Vt., and Arlen Specter, R-Pa., and from conservatives such as Sens. Connie Mack, R-Fla., Strom Thurmond, R-S.C., and McCain. To win restrictions, Smith and his allies must win support from these Republicans and from some Democrats, such as Sen. John Breaux, D-La.

In any debate on possible curbs, the researchers and patients' groups will be aided by abortion-rights advocates, including Planned Parenthood and the New York City-based Center for Reproductive Law and Policy. Last year, the two groups persuaded a federal judge to strike down a clause in the Arizona Constitution that bars research on fetal tissue. That lawsuit is heading for an appeal late this year in the 9th U.S. Circuit Court of Appeals in San Francisco.

Abortion-rights supporters dismiss suggestions of illegalities in the collection and transfer of fetal parts. Sandra Jordan, a spokeswoman for New York City-based Planned Parenthood Federation of America, said in early December that "there are not price tags attached to this. We are assuming it is a figment of [Crutcher's] imagination." In January, she said that seven chief executives of clinics that donate tissue discussed the matter in a late-December teleconference. "As far as we can determine," she added, "we are following the letter of the law."

Abortion-rights supporters are particularly critical of Crutcher because of his anti-abortion stand and his statement that he will produce testimony from at least one witness on the killing of two fetuses born alive at a clinic. Advocates for abortion clinics strenuously deny such charges. They say that Crutcher hopes to stigmatize abortion with false and ghoulish charges, and that he is hindering law enforcement by keeping secret the identity of the supposed witness.

Research supporters, including Waxman, Fantel, and Freed, generally share these criticisms of the anti-abortion groups. They complain that opponents of fetal-tissue research are motivated by "abortion politics" and want to entangle researchers and abortion providers in federal red tape.

Separating the fetal-tissue-research controversy from abortion politics may be impossible, said former Sen. Adams. "I don't see how you do it, because the abortion fight seems to overwhelm everything when you get into it."

There is still plenty of room for a cosmetic compromise that won't significantly curb research or abortions, mostly because Republicans are unwilling to cross their backers in the high-tech industry, says author Suzanne Rini.

Smith disagreed: "We will go as far we can to pass something."

Indeed, Waxman, the House's most prominent supporter of fetal-tissue research, said he might accept stricter oversight and an extension of government ethics rules to private researchers -- if the allegations made by anti-abortion advocates prove to be true. Still, such restrictions should not curb the great promise of medical research that uses fetal tissue, he said. As for the companies that sell tissue, he said, "they should be prosecuted. ... Any price is unreasonable and illegal."

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