

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

FILED
U.S. DISTRICT COURT
INDIANAPOLIS DIVISION

16 MAY 25 PM 12:38

SOUTHERN DISTRICT
OF INDIANA
LAURA A. BRIGGS
CLERK

TRUSTEES OF INDIANA UNIVERSITY,)
FRED H. CATE, and its research faculty, DR.)
BRUCE LAMB and)
DR. DEBOMOY LAHIRI,)
)
Plaintiffs,)
)
v.)
)
PROSECUTOR OF MARION COUNTY)
INDIANA, in his official capacity,)
)
Defendant.)

1 : 16 - CV - 1289 JMS - DML

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF / NOTICE OF
CHALLENGE TO CONSTITUTIONALITY OF INDIANA STATUTE

PARTIES

1. The Board of Trustees of Indiana University ("IU") is a body politic under the laws of the state of Indiana. IU brings this action on its own behalf and on behalf of its affected employees and students.

2. Fred H. Cate, J.D., is IU's Vice President for Research. Cate is responsible for and has authority over all aspects of IU's research university-wide, including obtaining grant funding, research compliance, scientific integrity, and administration of grants.

3. Dr. Bruce Lamb, Ph.D., is a professor of Medical and Molecular Genetics at the Indiana University School of Medicine. He holds the Roberts Family Chair in Alzheimer's Disease Research and serves as the Executive Director of Stark Neurosciences Research Institute ("Stark").

4. Dr. Debomoy Lahiri, Ph.D., is a professor of psychiatry and a Primary Investigator for Stark Neurosciences Research Institute.

5. Stark Neurosciences Research Institute is located in Marion County, Indiana.

6. The Prosecutor of Marion County, Indiana, is the duly elected prosecutor of the county in which IU facilities that perform fetal tissue research are located and the prosecutor is responsible for prosecuting crimes occurring in Marion County. He is sued in his official capacity and is designated by his official title pursuant to Fed. R. Civ. P. 17(d).

JURISDICTION AND VENUE

7. This Court has jurisdiction of this matter pursuant to 28 U.S.C. §§ 1331, 1343.

8. Venue is proper in this district pursuant to 28 U.S.C. § 1391.

9. Declaratory relief is authorized by 28 U.S.C. §§ 2201 and 2202 and by Rule 57 of the Federal Rules of Civil Procedure.

10. This action is brought pursuant to 42 U.S.C. § 1983 to redress the deprivation, under color of state law, of rights secured by the Constitution of the United States.

LEGAL AND FACTUAL BASIS FOR CLAIMS

Indiana University's Fetal Tissue Research

11. Current Indiana law allows persons to knowingly or intentionally purchase or sell a fetus to be used for adult or fetal stem cell research. Ind. Code § 35-46-5-3(b), (c)(2) ("human organism statute").

12. While the term "fetus" is not defined within the human organism statute, elsewhere in Title 35 (Indiana's criminal law title), fetus is defined as "a fetus that has attained viability". Ind. Code § 35-31.5-2-132.

13. Thus, the human organism statute permits a viable fetus to be used for adult or fetal stem cell research, whereas other prohibited uses of viable fetuses constitute the level five felony of “unlawful transfer of a human organism.” Ind. Code § 35-46-5-3(b), (c)(2).

14. The recently enacted Indiana House Enrolled Act No. 1337 (“Enrolled Act”) leaves the existing human organism statute unchanged, but adds a second level five felony (“unlawful transfer of fetal tissue”) for anyone who “intentionally acquires, receives, sells, or transfers fetal tissue,” defined as “tissue, organs, or any other part of an aborted fetus.” Ind. Code § 35-46-5-1.5 (“fetal tissue statute”).

15. That is, while one may lawfully purchase or sell an entire viable fetus for adult or fetal stem cell research, one may not, under the Enrolled Act, acquire, receive, sell, or transfer fetal *tissue*, whether or not the aborted fetus from which it is derived was viable.

16. The fetal tissue statute is broader than the unlawful transfer of a human organism statute in three ways.

17. First, the fetal tissue statute applies to any part of an aborted fetus (including fetal tissue), rather than only an entire fetus. Second, the fetal tissue statute applies whether or not the fetus from which the tissue is derived is viable. Third, the fetal tissue statute contains no exceptions for stem cell research or research of any type.

18. Another difference between the statutes is that the human organism statute requires purchase or sale, whereas the fetal tissue statute is violated through sale as well as noncommercial transmissions, including acquiring, receiving, or transferring.

19. IU and Dr. Lahiri currently conduct no research on whole, intact, fetuses from any stage of viability. IU and Dr. Lahiri do conduct research using fetal tissue that it acquires and receives from the Birth Defects Research Laboratory at the University of Washington (“U. Wa.

Lab"). The U. Wa. Lab advises that fetal tissue is obtained from both elective abortions and miscarriages.

20. From that fetal tissue, Dr. Lahiri derives mixed cell cultures that form the basis of his research in Alzheimer's disease. Dr. Lahiri is involved with multiple ongoing collaborative research projects and educational initiatives, including the NIH-funded Alzheimer's Disease Center (one of 30 funded nationally). As one aspect of his research, Dr. Lahiri has done a great deal of work on biochemical contrasts between autism spectrum disorder (ASD) and Alzheimer's disease.

21. Dr. Lahiri also derives mixed cell cultures from fetal tissue and for use by collaborators across IUSM and at other institutions. That work is performed at Dr. Lahiri's laboratory.

22. IU and Dr. Lamb, as director of Stark, also possess in many of its laboratories "biologicals" (such as RNA, DNA, and proteins) that may potentially have been derived from fetal tissue. Some of these biologicals have been stored in a frozen state by IU for many years. It would be impossible to ascertain the initial derivation for most if not all of these biologicals.

23. There are a variety of circumstances under which IU, Dr. Lahiri, or Dr. Lamb, as director of Stark, may need to "transfer" cells or biologicals that were derived from fetal tissue.

24. As a condition of most NIH grants, IU, Dr. Lahiri, and Dr. Lamb, as director of Stark, must agree to retain the samples used in its research. IU, Dr. Lahiri, and Dr. Lamb, as director of Stark, must also agree to share those samples upon request with the NIH or other institutions that are interested in reproducing or authenticating IU or Dr. Lahiri's research results. If IU, Dr. Lahiri, or Dr. Lamb, as director of Stark, are unable to comply with NIH's requirements with respect to sharing tissue samples and/or cells derived from such samples for

purposes of affirming the reproducibility of research results without violating Indiana law, IU and Dr. Lahiri's eligibility for NIH funding is likely to be severely limited. IU or Dr. Lahiri may also potentially have to refund millions of dollars in existing research grants.

25. When researchers join or separate from IU, they transfer their laboratory materials with them. Therefore, even were Dr. Lahiri to stop doing his research in the state of Indiana as a result of the Enrolled Act, he runs the risk that the mere act of transferring his research to another institution would constitute a felony.

26. At the most literal level, IU, Dr. Lahiri, and Dr. Lamb, as director of Stark, must "transfer" fetal tissue within and among its laboratories.

27. IU, Cate, Dr. Lahiri, and Dr. Lamb, as director of Stark, are unable to discern which, if any, of their current research activities, are prohibited by the Enrolled Act. To the extent the Enrolled Act criminalizes ongoing research, it impairs Dr. Lahiri's academic freedom to perform research into an important matter of public health.

28. The Enrolled Act's burdens on IU, Cate, Dr. Lahiri, and Dr. Lamb, as director of Stark far outweigh any benefit to the State of Indiana.

29. Cate and Dr. Lamb are responsible for attracting research faculty to IU's Stark Neurosciences Research Institute. They have significant concerns that the Enrolled Act's limitations on academic research using fetal tissue and cells derived from fetal tissue will deter potential candidates from coming to Indiana to join Stark.

30. In addition, Cate and Dr. Lamb believe that the negative impact on Stark's research would be dramatic and lead to difficulties in renewing the NIH-funded Alzheimer's Disease Center that would be catastrophic for both Stark and neuroscience research more generally at the Indiana University School of Medicine.

31. Cate, Dr. Lamb, and Dr. Lahiri also believe that the Enrolled Act will slow the pace of research using fetal tissue, which could delay an important breakthrough in treatments and cures to patients with a variety of debilitating neurological disorders.

LEGAL CLAIMS

32. The Enrolled Act's criminalization of acquiring, receiving, selling, or transferring fetal tissue is unconstitutionally vague.

33. The Enrolled Act's restrictions on acquiring, receiving, selling, or transferring fetal tissue place an excessive burden on interstate commerce which is not outweighed by any benefit of the Enrolled Act.

34. The Enrolled Act's restrictions on acquiring, receiving, selling, or transferring fetal tissue violate Dr. Lahiri's First Amendment right to academic freedom with respect to his research on a matter of public concern.

REQUEST FOR RELIEF

WHEREFORE, plaintiffs request that this Court:

1. Accept jurisdiction of this case and set it for hearing at the earliest opportunity.
2. Declare House Enrolled Act 1337 is unconstitutional to the extent it:
 - a. Criminalizes intentionally acquiring, receiving, selling, or transferring fetal tissue used for research purposes. Ind. Code § 35-46-5-1.5.
3. Enter a preliminary injunction, later to be made permanent, against defendants from enforcing Indiana Code Ind. Code § 35-46-5-1.5 (eff. July 1, 2016).
4. Award plaintiffs their costs and reasonable attorneys' fees pursuant to 42 U.S.C. § 1988.
5. Award all other proper relief.

Respectfully submitted,

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