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FISCAL IMPACT REPORT

		ORIGINAL DATE	02/13/13		
SPONSOR	SPAC	LAST UPDATED	02/28/13	HB	

SHORT TITLE Biomedical Research Act

SB CS/313/aSJC

ANALYST Trowbridge

ESTIMATED ADDITIONAL OPERATING BUDGET IMPACT (dollars in thousands)

	FY13	FY14	FY15	3 Year Total Cost	Recurring or Nonrecurring	Fund Affected
Total		NFI	NFI	NFI	N/A	N/A

(Parenthesis () Indicate Expenditure Decreases)

SOURCES OF INFORMATION

LFC Files

<u>Responses Received From</u> University of New Mexico (UNM) Department of Health (DOH) Attorney General's Office (AGO)

SUMMARY

Synopsis of SJC Amendment

The Senate Judiciary Committee amendment to the Senate Public Affairs Committee substitute for Senate Bill 313 does the following:

On page 5, line 8, after "than", strikes the remainder of the line, and strikes line 9 through "(\$25,000)" and inserts in lieu thereof "one thousand dollars (\$1,000)". This changes the fine amount to not more than \$1,000.00.

Synopsis of Original Bill

The Senate Public Affairs Committee substitute for Senate Bill 313 (SB 313) would permit biomedical research and clinical applications involving the derivation and use of 1) stem cells derived from pre-implantation human embryonic stem cells produced by in vitro fertilization clinics and designated for destruction 2) stem cell lines, 3) adult stem cells from any source, 4) umbilical stem cells, and 5) placental cells.

SB 313 would require that research involving the derivation of human embryonic stem cells have the informed consent of the original progenitors or recipients pursuant to a sperm or egg donation agreement.

Senate Bill CS/313/SJC – Page 2

SB 313 would require that research involving the derivation of human embryonic stem cells be performed in accordance with guidelines and policies promulgated by the U.S. Department of Health and Human Services Office for Human Research Protection, the National Research Council and the National Academy of Sciences Institute of Medicine.

SB 313 defines the terms 'embryo' and 'fetus' and would set limits on the length of time that intact human embryos may be cultured in vitro for research. SB 313s would also ban human cloning and would prohibit the knowing creation of an embryo, by means of fertilization, for the sole intent of donating the embryo for research or for cloning.

SB 313 states that an employee shall not be required to conduct research or experimentation on the creation or use of pre-implantation embryos in relation to human embryonic stem cell research when such research conflicts with religious practices and beliefs of the employee.

SB 313 would also amend the Maternal, Fetal and Infant Experimentation Act (Chapter 24, Article 9A NMSA 1978) to permit biomedical research on limited categories of human embryonic stem cells, prohibit human cloning and would set penalties for violation of its provisions.

FISCAL IMPLICATIONS

The agencies report no fiscal impact on state government. The University of New Mexico (UNM) indicates that this bill will allow faculty at universities in New Mexico to more competitively apply for federal funding for stem cell research.

SIGNIFICANT ISSUES

The Attorney General's Office (AGO) notes that SB 313 prohibits "human reproductive cloning," which the bill defines as "the asexual creation of an embryo." This definition has an internal contradiction. The bill's definition of "embryo" is "a fertilized human egg...." If an embryo is a fertilized human egg, then an embryo cannot be created "asexually," as stated in the definition of "human reproductive cloning," because "asexual" means without fertilization.

The Department of Health (DOH) reports that human stem cells are widely believed to hold a great deal of promise for the understanding and treatment of many of the major acute and chronic developmental and degenerative diseases affecting society that are caused by loss or damage to cells. Because of their potential to divide and specialize into many different cells types, stem cells have great potential for use in repairing damaged tissues to recover lost function. The ability of stem cells to be re-directed toward the development of different cells varies depending upon the source of the stem cell. While adult stem cells are believed to have more limited potential than embryonic, placental and amniotic stem cells, very recent research developments in animal models suggest that adult-derived stem cells might have broader usage than previously assumed.

Additionally, the DOH states that at the present time human stem cell researchers work in an environment of general Federal guidelines with a number of absolute restrictions. SB 313 would create specific guidelines for researchers studying human stem cells in the State of New Mexico toward the goal of fostering such biomedical research within New Mexico. At the same time, SB 313 would offer protections against human reproductive cloning and activities supporting human cloning, and prohibits the creation of human embryos by fertilization (sexual production by sperm and egg) solely for the purpose of donating to research.

OTHER SUBSTANTIVE ISSUES

The UNM provided the table below:

NIH Stem Cell Research Funding, FY 2002–2011

	FY 2002	2–FY 2011 (Dollars in milli	ons)		
	Huma	n Stem Cells	Non-Human Stem Cells		
Year	Embryonic	Non-Embryonic	Embryonic	Non-Embryonic	
2002	\$10.1	\$170.9	\$71.5	\$134.1	
2003	\$20.3	\$190.7	\$113.5	\$192.1	
2004	\$24.3	\$203.2	\$89.3	\$235.7	
2005	\$39.6	\$199.4	\$97.1	\$273.2	
2006	\$37.8	\$206.1	\$110.4	\$288.7	
2007	\$42.1	\$203.5	\$105.9	\$305.9	
2008	\$88.1	\$297.2	\$149.7	\$497.4	
2009 (Non-ARRA)	\$119.9	\$339.3	\$148.1	\$550.2	
2009 (ARRA)	\$22.7	\$57.9	\$29.1	\$88.1	
2010 (Non-ARRA)	\$125.5	\$340.8	\$175.3	\$569.6	
2010 (ARRA)	\$39.7	\$73.6	\$19.6	\$74.2	
2011	\$123.0	\$394.6	\$164.6	\$619.9	

OTHER SUBSTANTIVE ISSUES

The DOH reports that SB 313 added a clause in Section 8 that may conflict with Section 3 of the bill, confusing the intent and interpretation of the bill and possibly even negating the intent and interpretation of the bill. Page 3, lines 9-10 under Section 3.A.1, states that clinical research is permitted on pre-implantation human embryonic stem cells provided that they are derived from "embryos that are produced by in vitro fertilization clinics and designated for destruction." However, on page 6, lines 6-8 under Section 8.D, SB 313 states that clinical research is defined as <u>not</u> including human in vitro fertilization performed to treat infertility, "provided that this procedure shall include provisions to ensure that each living fertilized ovum, zygote or embryo is implanted in a human female recipient."

The DOH also indicates that the intent and impact of the addition of the clause, "provided that this procedure shall include provisions to ensure that each living fertilized ovum, zygote or embryo is implanted in a human female recipient" by the Senate Public Affairs Committee in its substitute to SB 313 is unclear and may conflict with Section 3.A.1.

WHAT WILL BE THE CONSEQUENCES OF NOT ENACTING THIS BILL

The AGO and DOH indicate that the restrictions of the Maternal, Fetal and Infant Experimentation Act would continue to prohibit the use of human embryos, including human embryonic stem cells, for clinical research.

TT/svb