GRS GOVERNMENT RELATIONS STRATEGIES

TO: Members of the House Health Care Committee

FROM: Hasina E. Squires on behalf of MedCure & BioGift

DATE: April 15, 2013

RE: **House Bill 3345 Testimony**

Members of the House Health Care Committee Committee, thank you for the opportunity to appear before you today to provide testimony regarding HB 3345. For the record my name is Hasina Squires and I appear before you today on behalf of my clients MedCure and BioGift.

Both MedCure and BioGift currently operate as nontransplant anatomical research and recovery organizations in east Multnomah County. Although they are competitors their offices are located within a mile of eachother and they are here today united in their comments regarding HB 3345. MedCure and BioGift are the only entities within the State of Oregon operating as nontransplant anatomical research and recovery organizations. HB 3345's proposed amendments will license and regulate these two entities under the Oregon Health Authority.

I have attached a summary of the most recent amendments that the sponsor of the bill (Representative Hoyle) provided me with in advance of today's hearing (-6 amendment). Representative Hoyle and her staff have been working on additional amendments and I expect those to be forth coming but for purposes of today's hearing I will focus my comments on the -6 amendments.

My clients have the following comments regarding the proposed -6 amendment.

Under the provisions of HB 3345 -6 amendment a non transplant anatomical research and recovery organization must be accredited by a national organization (that organization must require certain items in order to qualify as an accredited organization). Previous amendments contained objectionable/unclear requirements. The -6 amendment has removed our concerns regarding accrediting organizations' minimum requirements.

We appreciate the fact that the -6 differs from the original bill by placing the regulation within the Oregon Health Authority rather than the Oregon Mortuary and Cemetery Board. Tissue banks are currently regulated under the Oregon Health Authority and we believe our industry should be regulated by the Oregon Health Authority.

P.O. Box 1745 • Lake Oswego, OR 97035 • Phone 503-321-5116 • Fax 503-321-5117 • hasina@grsoregon.com • www.grsoregon.com

Under Section 2 (3) fees will be adopted by rule. My client is interested what those fees will be.

Section 3 (b) and (c) which requires name and address of persons who had possession of the anatomical material to be documented has caused my clients to raise the issue of whether or not the documentation will be made public record (for example at least one of my clients does work with the Department of Defense and they believe that some individuals who receive my client's anatomical material may not necessarily want to appear on a public list).

Section 4 allows the OHA to inspect the premises and records as "reasonably necessary". What is the definition of reasonably necessary? Annually or biennially?

Section 5 allows civil penalties not to exceed $1,000 o be assessed for violations. Civil penalties typically cause concern for many parties. A penalty objectionable to an entity it can look onerous.

My clients do not object to regulations that make sense and while HB 3345 -6 attempts to provide reasonable regulation of our industry

Thank you for the opportunity to appear before you today I would be happy to answer any questions the committee may have.

HB 3345 -6 SUMMARY

PREPARED BY: HASINA E. SQUIRES, GOVERNMENT RELATIONS STRATEGIES

Section 1—Definitions & exclusion of facilities providing postmortem exams, public corporations and public/private institutions of higher education.

Section 2 (1)—Require nontransplant anatomical research recovery organization to:

1) Be licensed by the Oregon Health Authority;

2) Obtain a waiver (waiver granted if entity is licensed, accredited or regulated under federal or state law to recover or distribute anatomical material for transplant or therapy purposes); or

3) Be accredited by a "qualified" nontransplant anatomical research recovery organization.

Section 2 (2)—Require accredited nontransplant anatomical research recovery organizations to:

1) Require documentation of processes related to recovery, and handling of distribution of anatomical material
2) Require records to be maintained for at least 10 years
3) Conduct onsite compliance inspections of records, processes and materials relating to:
    a) Donor intake
    b) Acquisition, preparation, labeling, packaging, storage and distribution of anatomical material
    c) Facility inspection

Section 2 (3)—Adopt fees and application process by rule

Section 2 (4)—Specify that license expires after two years

Section 2 (5)—Provides license required under HB 3345 is not in lieu of other licenses

Section 2 (6)—Require fees collected are appropriated for functions of HB 3345

Section 3 (1)—Require nontransplant anatomical research recovery organization to maintain record of each donor that includes:

1) Donor documentation that anatomical material was noted for research or education
2) Name and address of each person that had possession of material
3) Documentation of name and address of each person that receives the anatomical material

Section 3 (2)—Require that any anatomical material returned to donor relative/representative discloses whether all or part of the donor's body is being returned.

Section 3 (3)—Require unreturned anatomical remains to be properly disposed of

Section 3 (4)—Require nontransplant anatomical research recovery organization to provide clear notice regarding guaranteed coverage of cost related to transporting and disposing of anatomical material

Section 4—Allow Oregon Health Authority to inspect premises and records of nontransplant anatomical research recovery organization

Section 5—Allow for maximum civil penalties of $1,000 for each violation, license revocation, penalties are appropriated for functions of HB 3345

Section 6—Exempts nontransplant anatomical research recovery organization from funeral, cemeteries and crematorium ORS Chapter 692

Section 7—Grandfathers existing nontransplant anatomical research recovery organizations from provisions of HB 3345 until July 1, 2014

Section 8—Provide operative date of HB 3345 as January 1, 2014 and allows Oregon Health Authority to take actions to implement HB 3345 prior to effective date

Section 9—Emergency clause