

**DEPARTMENT OF HEALTH AND HOSPITALS**

LOUISIANA STATE BOARD  
OF MEDICAL EXAMINERS  
(La. Rev. Stat. §§37:1261-92)

**STATEMENT OF POSITION**

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The Use of Non-FDA Approved  
Stem Cell Products  
[February 18, 2013]

**BACKGROUND.** The Louisiana State Board of Medical Examiners (the "Board") has received information that reveals that some physicians in this state are offering stem cell products for the treatment of various conditions without medical indication of their safety or efficacy. In some instances, these products have not been approved by the U.S. Food and Drug Administration; in others they are being offered outside of approved research protocols.

In response to such information, and its own subsequent investigations, the Board decided that more information was needed and appointed a committee to advise the Board with respect to how it might best protect the public with respect to the use of these products.

Following a review of the committee's report and its consideration and discussion of the issue, the Board is concerned that the interest in stem cells for the treatment of various conditions that do not respond to current therapies, and the uncertainty as to the safety and efficacy associated with their use, may leave patients susceptible to stem cell treatments that are unproven and potentially harmful and subject them to financial exploitation. Accordingly, the Board believes it appropriate for the protection of the health, safety and welfare of the citizens of this state, and the physicians who provide their medical care, to formally express its views on the subject.

**GOAL.** In announcing this Statement it is the intent of the Board to: (i) protect the public from unproven stem cell treatments that may be harmful and from financial exploitation which is unethical; (ii) provide guidance to Louisiana physicians seeking to provide quality care to their patients; and (iii) to promote compliance with federal regulations in this area.

**FINDINGS.** Initially, the Board recognizes that stem cell therapies hold great potential for the treatment of many serious diseases and conditions and in some instances have become the standard of care. However, it is well-established that there are significant risks associated with the administration of unproven products of this type. Thus, while the development of stem cell based therapies for other conditions is greatly needed, the availability of such products must necessarily await the results of research which demonstrates that they are safe and effective.

In the meantime commercial application of tissue based stem cell products are being marketed to physicians in Louisiana and elsewhere for the treatment of a variety of medical conditions ranging from life-threatening to cosmetic and regenerative. Identified as "HCT/P" or "human cells, tissues, and cellular

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or tissue-based products,"<sup>1</sup> the U.S. Food and Drug Administration (the "FDA") considers these products to be drugs and/or biologics and regulates them as such.<sup>2</sup>

Among other items, FDA regulations provide: (i) that tissue-based stem cell products may not be administered to patients in the absence of an FDA approved indication or approved research protocol; (ii) that in order to investigate the use of a stem cell based product in humans, an investigational new drug application that reports data from preclinical studies on the likely safety and efficacy of the investigational product must be filed with the FDA; and (iii) strict limitations with respect to charging patients for a clinical trial sponsor's drug.<sup>3</sup>

Utilizing a stem cell product, or any product for that matter, that has not been shown to be safe and effective is inconsistent with good medical practices, contrary to the standard of care,<sup>4</sup> and is unethical.<sup>5</sup>

Engaging in unethical conduct, as defined by the American Medical Association's Code of Medical Ethics, constitutes unprofessional conduct and conduct in contravention of the Board's rules<sup>6</sup> and the

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<sup>1</sup>21 C.F.R. §1271.3(d).

<sup>2</sup>The FDA regulates the use of stem cells under the authority of the Federal Food, Drug and Cosmetic Act ("FFDC Act"), the Public Health Service Act ("PSH Act"), and Title 21 of the Code of Federal Regulations ("C.F.R.").

<sup>3</sup>The FDA has established a graduated approach to the regulation of stem cell products which is apparently designed to increase safety and prevent the introduction, transmission and spread of communicable disease, while minimizing regulatory burdens. Under the regulations, certain stem cell products *e.g.*, those that are 'minimally manipulated' as defined by 21 C.F.R. §1271.3(f) and meet all other requirements prescribed by federal regulation (*See e.g.*, 21 C.F.R. §1271.10), are regulated under Section 361 of the PHS Act (42 U.S.C. §264) and FDA regulations set forth in 21 C.F.R. Part 1271. Premarket approval is not required for these (361 HCT/P) products, although other regulations apply. Stem cell products that do not satisfy the requirements for Section 361 regulation, or meet an exception provided by federal regulation, are considered to be drugs, devices and/or biological products and are regulated as such under the FFDC Act, 21 U.S.C. §301 *et seq.* and/or §351 of the PHS Act (42 U.S.C. §262), as well as the applicable regulations in Title 21 of the C.F.R. *See e.g.*, 21 C.F.R. §1271.20; FDA Guidance, *Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) Small Entity Compliance Guide*, <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/ucm073366.htm>.

<sup>4</sup>The Board does not consider the use of stem cells products to constitute integrative or complementary medicine, as defined in its rules, LAC 46XLV.7101 *et seq.*

<sup>5</sup>The AMA Code of Medical Ethics provides that it is unethical for a physician to: (i) provide treatments which have no medical indication and offer no possible benefit to the patient; (ii) which are prohibited by regulation or law; (iii) participate in clinical investigation unless such activities are a part of a systematic program competently designed under accepted standards of scientific research to produce data that is scientifically valid and significant; or (iv) to charge or collect an illegal or excessive fee. *See*: AMA Code of Medical Ethics, Opinion Nos. 8.20; 6.05; 2.07, respectively.

<sup>6</sup>The Board's rules on unprofessional conduct, LAC 46:XLV.7603A and 7603A(6) provide, in pertinent part: 'A. [I]n the exercise of its duties the board has determined to define the term *unprofessional conduct*, as set forth in La. Rev. Stat. §37:1285(A)(13), as '[C]onduct that includes but is not limited to the departure from, or the failure to conform to, the standards of acceptable and prevailing medical practice or the ethics of the medical profession including, but not limited to, the principles established by the American Medical Association, the American Osteopathic Association, and relevant medical specialty associations, or the commission of any act contrary to honesty, justice, good morals, patient safety or the best interest of the patient, whether committed in the course of the physician's practice or otherwise, and whether committed within or without of this state;' and 'A.6. *Exercising Undue Influence*—physicians shall exercise their professional judgment in the best interest of their patients. A physician shall not: . . . b. perform, or refer a patient to another to perform, unnecessary tests, examinations or services which have no legitimate medical purpose.'

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Louisiana Medical Practice Act.<sup>7</sup> In short, it is unethical for a physician to utilize stem cells products that: (i) have no medical indication; (ii) offer no possible benefit; (iii) have not been approved by the FDA; or (iv) are offered outside of an approved FDA research protocol; or (v) to charge an illegal or excessive fee for their use. Thus, aside being subject to administrative, civil or criminal penalties as a result of failing to adhere to federal law and/or regulation,<sup>8</sup> a physician who engages in such conduct may also be subject to disciplinary action against his or her license by the Board.<sup>9</sup>

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*Guidance to Physicians.* For purposes of this Statement the term *stem cells*: (a) *includes* tissue specific stem cells, adipose derived stem cells, bone marrow mesenchymal stem cells, multipotent cells, pluripotent cells, regenerative cells, embryonic stem cells and other cells of the same type, as such terms are defined from time to time by regulations promulgated by the FDA; (b) *does not include* blood products which are separately regulated by the FDA *e.g.*, red blood cells, platelets, plasma, *etc.* or tissues such as skin, bone and other tissues of the same type.

1. Physicians considering the use of stem cell products in the treatment of their patients should ensure compliance with federal and state laws and regulations including restrictions that apply to embryonic stem cells<sup>10</sup> that go above and beyond those that apply to adult stem cells.<sup>11</sup>

Stem cell products should not be utilized unless .the FDA has:

- a. approved the use of stem cell product (label or off label use) or
- b. approved the stem cell product as an investigational new drug *and* the patient is enrolled in an FDA approved clinical trial or study or
- c. issued a permissive use disclaimer for the product or
- d. exempted the product from approval.

2. Physicians should only charge patients for treatment with stem cell products that are approved by the FDA (label and off label uses). In other cases, FDA guidelines for the recovery of unrelated costs should be followed.

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<sup>7</sup>Under the Louisiana Medical Practice Act (the "Act"), the Board may take action against the license of a physician as a result of: La. Rev. Stat. §37:1285(A): '(13) [U]nprofessional conduct;' and '(30) [V]iolation of any rules and regulations of the board, or any provisions of this Part.' The Board also may take action for '[C]ontinuing or recurring medical practice which fails to satisfy the prevailing and usually accepted standards of medical practice in this state.' La. Rev. Stat. §37:1285(A)(14).

<sup>8</sup>See: 21 C.F.R. Part 1271, 18 U.S.C. §§3559, 3571, and §368 of the PHS Act, 42 U.S.C. §271.

<sup>9</sup>Given the existing authority under the Act and the Board's rules noted hereinabove, the Board believes that this Statement, rather than a rule, is the appropriate mechanism to convey its views on this topic.

<sup>10</sup> La. Rev. Stat §9:122

<sup>11</sup>This Statement is not intended nor should be viewed as a definitive expression of federal law or regulations or state law concerning the use of stem cells including the use of embryonic stem cells. Physicians seeking to utilize such products should insure compliance with these requirements.

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*Guidance to Patients.* The FDA advises patients considering stem cell treatment to ask their physician if the FDA has approved the product or if he or she will be participating in an FDA regulated clinical study.<sup>12</sup> Patients who suspect that they are being treated with stem cell products in violation of federal or state law or regulation should contact the FDA, [www.fda.gov](http://www.fda.gov) 1-888-463-6332, or the Board, [www.lsbme.la.gov](http://www.lsbme.la.gov) "Investigations" (504) 568-6820.

**CONCLUSION.** The opinions expressed in this Statement, it must be emphasized, are not predicated on a medical determination that *all* stem cell treatments are improper or that *all* physicians or companies promoting and employing stem cell use are acting in an inappropriate manner. The FDA has approved some stem cell products and certain others that require no more than minimal manipulation fall outside of premarket administrative and/or clinical requirements that may otherwise apply. However, given the potential for patient harm and the possibility of patient exploitation from the use of untested, unregulated and expensive stem cell products that have not been shown to be safe and effective, the Board believes that it essential that physicians seeking to use stem cell products do so in compliance with the ethical tenets of the medical profession, the laws and rules administered by the Board and the requirements of federal law and regulation.

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<sup>12</sup>The FDA has issued warnings concerning the use of stem cell treatments. *See:* FDA Consumer Update (Aug. 9, 2012), [www.fda.gov/forconsumers/consumerupdates/ucm286155.htm](http://www.fda.gov/forconsumers/consumerupdates/ucm286155.htm).