

By: Senator(s) Harkins, Jackson (11th),  
Jordan

To: Public Health and  
Welfare

SENATE BILL NO. 2830

1 AN ACT TO AMEND SECTION 41-131-1, MISSISSIPPI CODE OF 1972,  
2 TO REVISE THE DEFINITION OF "ELIGIBLE PATIENT" TO INCLUDE THOSE  
3 PATIENTS WITH A TRAUMATIC INJURY; TO REVISE THE DEFINITION OF  
4 "INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE" TO INCLUDE  
5 ADULT AUTOLOGOUS MESENCHYMAL STEM CELL; AND FOR RELATED PURPOSES.

6 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MISSISSIPPI:

7 **SECTION 1.** Section 41-131-1, Mississippi Code of 1972, is  
8 amended as follows:

9 41-131-1. (1) This section shall be known and may be cited  
10 as the "Right-to-Try Act."

11 (2) For purposes of this section:

12 (a) "Eligible patient" means a person who meets all of  
13 the following requirements:

14 (i) Has a debilitating disability, traumatic  
15 injury, terminal illness or life-threatening illness that has not  
16 responded or cannot be treated with currently approved products;

17 (ii) Has considered all other treatment options  
18 currently approved by the United States Food and Drug



19 Administration and all relevant clinical trials conducted in this  
20 state;

21 (iii) Has received a prescription or  
22 recommendation from the person's physician for an adult autologous  
23 mesenchymal stem cell, investigational drug, biological product or  
24 device;

25 (iv) Has given written informed consent, which  
26 shall be at least as comprehensive as the consent used in clinical  
27 trials for the use of the adult autologous mesenchymal stem cell,  
28 investigational drug, biological product or device, or, if the  
29 patient is a minor or lacks the mental capacity to provide  
30 informed consent, a parent or legal guardian has given written  
31 informed consent on the patient's behalf; and

32 (v) Has documentation from the person's physician  
33 that the person has met all of the requirements of this  
34 subsection.

35 (b) "Adult autologous mesenchymal stem cell,  
36 investigational drug, biological product or device" means \* \* \* an  
37 adult autologous mesenchymal stem cell, drug, biological product  
38 or device, any of which are used to treat the patient's  
39 disability, traumatic injury or illness, and the use of which has  
40 been either described in a United States Food and Drug  
41 Administration/National Institutes of Health (FDA/NIH)  
42 approved-protocol or study, or approved by an institutional review  
43 board (IRB), or successfully completed a safety study. The drug,



44 product or device must be produced in a manner consistent with the  
45 quality standards of an adult autologous mesenchymal stem cell,  
46 investigational drug, biological product or device in the United  
47 States (i.e., standards required by an FDA-approved trial) and  
48 must show prior evidence of safe usage in humans in the United  
49 States or other countries. The adult autologous mesenchymal stem  
50 cell, investigational drug, biological product or device must have  
51 successfully completed phase one of a clinical trial but has not  
52 been approved for general use by the United States Food and Drug  
53 Administration and remains under investigation in a clinical  
54 trial. The term shall not include Schedule I controlled  
55 substances.

56 (c) "Terminal illness" means a disease that without  
57 life-sustaining procedures will result in death in the near future  
58 or a state of permanent unconsciousness from which recovery is  
59 unlikely.

60 (d) "Written informed consent" means a written document  
61 that is:

62 (i) Signed by the:

63 1. Patient;

64 2. Parent, if the patient is a minor;

65 3. Legal guardian; or

66 4. Patient advocate designated by the patient

67 under the Uniform Health-Care Decisions Act, Section 41-41-201 et

68 seq.; and



69 (ii) Attested to by the patient's physician and a  
70 witness and that, at a minimum, includes all of the following:

71 1. An explanation of the currently approved  
72 products and treatments for the disease or condition from which  
73 the patient suffers;

74 2. An attestation that the patient concurs  
75 with his or her physician in believing that all currently approved  
76 and conventionally recognized treatments are unlikely to prolong  
77 the patient's life;

78 3. Clear identification of the specific  
79 proposed adult autologous mesenchymal stem cell, investigational  
80 drug, biological product or device that the patient is seeking to  
81 use;

82 4. A description of the potentially best and  
83 worst outcomes of using the adult autologous mesenchymal stem  
84 cell, investigational drug, biological product or device and a  
85 realistic description of the most likely outcome. The description  
86 shall include the possibility that new, unanticipated, different,  
87 or worse symptoms might result and that death could be hastened by  
88 the proposed treatment. The description shall be based on the  
89 physician's knowledge of the proposed treatment in conjunction  
90 with an awareness of the patient's condition;

91 5. A statement that the patient's health plan  
92 or third-party administrator and provider are not obligated or  
93 required to pay for any cost of any adult autologous mesenchymal



94 stem cell, investigational drug, biological product or device or  
95 for any care or treatments consequent to the use of the adult  
96 autologous mesenchymal stem cell, investigational drug, biological  
97 product or device, unless they are specifically required to do so  
98 by law or contract;

99                   6. A statement that the patient's eligibility  
100 for hospice care may be withdrawn if the patient begins curative  
101 treatment with the adult autologous mesenchymal stem cell,  
102 investigational drug, biological product or device and that care  
103 may be reinstated if this treatment ends and the patient meets  
104 hospice eligibility requirements; and

105                   7. A statement that the patient understands  
106 that he or she is liable for all expenses consequent to the use of  
107 the adult autologous mesenchymal stem cell, investigational drug,  
108 biological product or device and that this liability extends to  
109 the patient's estate, unless a contract between the patient and  
110 the manufacturer of the adult autologous mesenchymal stem cell,  
111 drug, biological product or device states otherwise. The  
112 patient's health plan or third-party administrator are not liable  
113 for any outstanding debt related to the treatment or lack of  
114 insurance consequent to the use of the adult autologous  
115 mesenchymal stem cell, investigational drug, biological product or  
116 device.

117           (3) A manufacturer of an adult autologous mesenchymal stem  
118 cell, investigational drug, biological product or device may make



119 available the manufacturer's adult autologous mesenchymal stem  
120 cell, investigational drug, biological product or device to  
121 eligible patients under this section. This section does not  
122 require that a manufacturer make available an adult autologous  
123 mesenchymal stem cell, investigational drug, biological product or  
124 device to an eligible patient. A manufacturer may:

125 (a) Provide an adult autologous mesenchymal stem cell,  
126 investigational drug, biological product or device to an eligible  
127 patient without receiving compensation; or

128 (b) Require an eligible patient to pay the costs of or  
129 associated with the manufacture of the adult autologous  
130 mesenchymal stem cell, investigational drug, biological product or  
131 device.

132 (4) This section does not require a health care insurer to  
133 provide coverage for the cost of any adult autologous mesenchymal  
134 stem cell, investigational drug, biological product or device.  
135 However, a health care insurer may provide coverage for an adult  
136 autologous mesenchymal stem cell, investigational drug, biological  
137 product or device.

138 (5) This section does not require the Mississippi Department  
139 of Corrections or any other governmental agency to provide  
140 coverage for the cost of any investigational drug, biological  
141 product or device.



142 (6) This section does not require a licensed hospital or  
143 nursing home to provide new or additional services, unless  
144 approved by the hospital or facility.

145 (7) This section does not require a licensed physician to  
146 offer any adult autologous mesenchymal stem cell, investigational  
147 drug, biological product or device.

148 (8) Notwithstanding any other provision of law to the  
149 contrary, no state agency or regulatory board shall revoke, fail  
150 to renew, or take any other action against a physician's license  
151 under Section 73-25-1 et seq., or against a pharmacist's license  
152 under Section 73-21-71 et seq., based solely on the physician's or  
153 pharmacist's recommendation to an eligible patient regarding  
154 prescription for or treatment with an adult autologous mesenchymal  
155 stem cell, investigational drug, biological product or device.  
156 Action against a health care provider's Medicare certification  
157 based solely on the health care provider's recommendation that a  
158 patient have access to an adult autologous mesenchymal stem cell,  
159 investigational drug, biological product or device is prohibited.

160 (9) If the clinical trial is closed due to lack of efficacy  
161 or toxicity, the drug shall not be offered. If notice is given on  
162 an adult autologous mesenchymal stem cell, investigational drug,  
163 product or device taken by a patient outside of a clinical trial,  
164 the pharmaceutical company or patient's physician shall notify the  
165 patient of the information from the safety committee of the  
166 clinical trial.



167 (10) Except in the case of gross negligence or willful  
168 misconduct, the patient's health plan, third-party administrator,  
169 or any person who manufactures, imports, distributes, prescribes,  
170 dispenses, compounds or administers an adult autologous  
171 mesenchymal stem cell, investigational drug or device to an  
172 eligible patient with a terminal illness in accordance with this  
173 section shall not be liable in any action under state law for any  
174 loss, damage or injury arising out of, relating to, or resulting  
175 from:

176 (a) The design, development, clinical testing and  
177 investigation, manufacturing, labeling, distribution, sale,  
178 purchase, donation, dispensing, compounding, prescription,  
179 administration, or use of the drug or device; or

180 (b) The safety or effectiveness of the drug or device.

181 The immunity provided under this subsection (10) is fully  
182 applicable to the owner of a hospital or other licensed health  
183 care facility rendering services to an eligible patient where the  
184 investigational drug is used or purchased only with regard to the  
185 use of the adult autologous mesenchymal stem cell, investigational  
186 drug, biological product or device at the facility.

187 (11) If a provision of this section or its application to  
188 any person or circumstance is held invalid, the invalidity does  
189 not affect other provisions or applications of this section that  
190 can be given effect without the invalid provision or application,  
191 and to this end the provisions of this section are severable.





192           **SECTION 2.** This act shall take effect and be in force from  
193 and after its passage.

