

SUBJECT: Experimental Drug Therapies – Patient “Right to Try”

SUBMITTED BY: Missouri Society of the American College of Osteopathic Family Physicians

REFERRED TO: 2017 ACOFP Congress of Delegates

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RESOLUTION NO. 23

1 WHEREAS, “Right to Try” legislation permits a terminally ill patient to access an investigational  
2 treatment that has not received approval by the United States Food and Drug Administration  
3 (FDA), and  
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5 WHEREAS, “Right to Try” legislation has been passed in Missouri and is being discussed or has passed in  
6 most others, but federal laws and regulations may still prevent patient access to the  
7 investigational treatments, and  
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9 WHEREAS, terminally ill patients who have exhausted existing treatment options currently can join a  
10 clinical trial to access experimental treatments, the criteria for acceptance into these trials is often  
11 very rigorous, and  
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13 WHEREAS, terminally ill patients can apply for the Food and Drug Administration’s (FDA) compassionate  
14 use” exception, this is often a slow process not conducive to someone with a terminal illness, and  
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16 WHEREAS, producers of experimental drugs may be hesitant to offer drugs outside of clinical trials  
17 because they fear reporting negative and adverse effects could negatively impact future FDA  
18 approval of the drug; now, therefore be it  
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20 RESOLVED, that the American College of Osteopathic Family Physicians (ACOFP) supports the ability of  
21 terminally ill patients to access investigational treatments that have passed Phase 1 clinical trials  
22 of the Food and Drug Administration approval process for their disease if the patient has  
23 exhausted approved treatments and gives informed consent, and further be it  
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25 RESOLVED, that since such experimental therapies in terminally ill patients are highly unlikely to  
26 fundamentally alter the course of their disease, physicians and drug manufacturers should be  
27 protected from legal action by patients who choose to try an investigative treatment but  
28 experience adverse effects or no noticeable improvements in their condition, and further be it  
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30 RESOLVED, that physicians be protected from legal liability for not informing patients of potential  
31 experimental therapies as experimental/investigational therapies have not yet been accepted as  
32 meeting the appropriate standard of care, and further be it  
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34 RESOLVED, that the ACOFP support “Right to Try” legislation at the federal level that protects the  
35 patient, physician and drug manufacturer, and further be it  
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37 RESOLVED that the ACOFP work with the United States Food and Drug Administration to simplify and  
38 expedite the application and approval process of terminally ill patients seeking a compassionate  
39 use exception for investigational treatments.