Governor's Advisory Council for Exceptional Citizens (GACEC)
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MEMORANDUM

DATE: **April 22, 2015**

TO: **The Honorable Members of the Delaware General Assembly**

FROM: **Robert D. Overmiller, Chairperson**
GACEC

RE: **Senate Bill No. 38 ("Right to Try" Act)**

The Governor's Advisory Council for Exceptional Citizens (GACEC) has reviewed **Senate Bill No. 38** which will allow a terminally ill patient and his or her treating physician, to decide if they will pursue treatment with an investigational drug, biological product or device, which has successfully completed Phase One of a clinical trial. The GACEC **endorses** the proposed legislation.

There are several safeguards in the bill, including a determination of the treating physician that the patient lacks comparable or satisfactory treatment options approved by the FDA (lines 19-21). Informed consent is comprehensively defined (lines 34-55). A parent may consent for a minor; a guardian may consent for a ward (lines 24-26). According to a February 13, 2015 article, similar "Right to Try" legislation has been introduced in 26 other states and enacted in Arizona, Colorado, Louisiana, Michigan, and Missouri.

There are a few potential adverse consequences to the bill. For example, there is a possibility that manufacturers of the investigational drugs, products and devices will be motivated to market them at high cost to desperate individuals despite a lack of proven benefit. Since insurers are not required to cover the costs of investigational drugs, products, and devices, it may also result in greater access by the wealthy to remedies in short supply (lines 47-48).

On the other hand, the articles note that FDA approval is an extended process which can result in lack of access to promising drugs. Moreover, only a very small percentage of patients are eligible to participate in clinical trials. Finally, positive and negative results may facilitate the approval review process. Council believes that the advantages of access by terminally ill patients to products which have successfully passed Phase One of a clinical trial outweigh negative considerations.

Thank you for your time and consideration of our observations. Please feel free to contact me or Wendy Strauss should you have any questions.