

HOSPICE & PALLIATIVE CARE

ASSOCIATION OF MICHIGAN

Michigan House of Representatives

Health Policy Committee

SB 991 / HB 5651 – Right to Try

The Hospice and Palliative Care Association of Michigan offers the following commentary on the proposed legislation regarding experimental treatments for consideration by the Michigan House of Representatives Health Policy Committee.

- HPCAM believes equal value should be placed on the comfort and care of all patients, including those with a terminal illness. HPCAM is concerned the legislation could be interpreted by some to suggest that it is acceptable to offer unproven or even harmful therapeutic interventions to the terminally ill patients in circumstances where it would be unethical to do so to a healthy patient. We believe that ethical oversight is important to any decision on whether to make experimental treatments available, particularly when a vulnerable population is involved. The legislation has no provision for ethical oversight and proposes to make drugs available outside the rigorous oversight that occurs in a clinical trial with human research subjects.

Because this legislation is restricted to the terminally ill, many who are going blind, becoming demented or losing their ability to walk are not included. If expansion of compassionate use and/or experimental treatments is considered, shouldn't all with a chronic, debilitating disease or condition be allowed to pursue these potentially beneficial treatments? This legislation fails to recognize those plights and merely places terminally ill individuals in the midst of a political debate.

- The legislation limits access to hospice and palliative care supports and services that could be utilized by both patient and family to support the symptoms and emotional needs of these individuals as they cope with the terminal condition.
- The legislation, as presented by the Goldwater Institute, does not guarantee patients/families access to experimental treatment and/or medications and, in fact, could potentially limit further the availability of experimental therapies more than they are currently.

It has been found in states that have already passed this blanket legislation that families are not accessing treatments or medications as they had anticipated. States cannot trump federal drug regulatory authority. The compassionate use provision, officially known as “expanded access to investigational drugs outside of a clinical trial,” already allows for companies to provide experimental drugs, if available, on a case-by-case basis, and with FDA’s approval. Even with the federal provision, companies are not compelled to provide the drug. **A state law does nothing to change the federal regulatory authority, nor does it impact or dictate pharmaceutical company compliance with federal regulatory requirements.**

- Pharmaceutical companies have programs and processes in place to allow for special dispensation of yet-to-be approved medications for humanitarian purposes. The process may not be ideal but it offers physicians and families an opportunity to discuss the potential benefits and complications that can arise from utilization of a treatment not fully tested.
- Drug companies are not required to dispense experimental medications or treatments at the direction of the requesting patient – even with this legislation in place. As a result, some patients may believe they have treatment options that are, in fact, not available. This is potentially more harmful to the patient/family.

If the drug or treatment an individual wants is expensive, this law only gives you the right to beg for it. Drug and device companies are under no obligation to give patients anything — no matter how sick they are.

- It may also limit or interfere with enrollment of patients into clinical trials. Most clinical trials randomize patients to either the drug being studied or a placebo in order to test efficacy of the trial drug. If patients have access to drugs outside of the trial they may opt not to participate because half of the patients in the trial receive a placebo. This could make testing new drugs more expensive and time consuming and thus inhibiting ultimate approval of potentially beneficial medications and treatments to all patients.
- HPCAM is concerned that this law does not address the knowledge gap of physicians who may not be aware of what is available for patients/families in the way of compassionate use. The law does nothing to fix or grant access to information to physicians to better navigate research protocols.
- An unfortunate, unintended consequence of increased access to unapproved therapies is the very real possibility that patients could choose to access dangerous and harmful compounds without any tangible potential benefit, thus significantly impairing the opportunity of experiencing a comfortable, meaningful end of life experience. The choice of these therapies would be predicated on a theory or promise, without any real tangible evidence of benefit -- these decisions would almost certainly be made in the context of emotional desperation.

The Hospice and Palliative Care Association of Michigan is concerned that passage of this legislation gives the wrong message to chronically ill, terminally ill patients and their families. It potentially provides false hope and offers no safety measures to ensure that experimental treatments pursued are not more harmful or causing more pain/suffering.

We support honest, frank discussions about terminal conditions, symptoms and prognosis to allow patients and families to make educated decisions about their treatment and quality of life. If, within those conversations, the opportunity to pursue experimental treatment is presented, we hope that medical professionals, patients and families will work cooperatively with

pharmaceutical companies to ensure safe, accountable care is provided via the means outlined in the compassionate use regulations.

We appreciate the intent of this legislation and hope that Michigan legislators consider the potential for negative impact on terminally ill patients/families this may bring and should consider whether this bill fully addressed the range of issues raised.

We encourage the Senate Health Policy Committee to determine what the purpose of putting through this legislation serves and if the outcomes you desire will be fulfilled via legislation as presented.

Respectfully submitted,

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