Testimony to Kansas House of Representatives Standing Committee on Health and Human Services on HB 2004, *Right to Try*

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Room 546-S

Chairman Hawkins, Members of the Committee, thank you for the opportunity to present these comments on the *Right to Try Legislation* (HB 2004).

About halfway through Pope Francis' 2013 encyclical Evangelii Gaudium (the Joy of the Gospel) the pontiff exhorts us to recognize that **realities are more important than ideas**. In fact, he titles this section of his letter: "Realities are more important than ideas"[1].

He reminds us that it is dangerous to dwell in the realm of words, images and rhetoric alone. He asks us to reject "objectives more ideal than real."

You may be wondering what the Pope's letter has to do with the "Right to Try" legislation. Let me explain.

This proposed legislation is a grand idea. Laudable; noble even if a bit quixotic. In fact, it's an idea that we may admire and aspire to, but the world of reality bends its merits to questionable decisions that may disrupt the safe delivery of care to the most vulnerable population that healthcare professionals are called to serve.

First let me acknowledge the laudable aspects of the bill. In bioethics there is a concept known as the Rule of Rescue that was first described in the mid-1980s by philosopher and bioethicist, AR Jonsen. At the time he was involved in some heated debates about rationing healthcare services in the U.S. Jonsen argued that there was a "common barrier" to the pure cost-effective allocation of resources in health care. He wrote:

> **Our moral response to the imminence of death demands that we rescue the doomed. We throw a rope to the drowning, rush into burning buildings to snatch the entrapped, dispatch teams to search for the snowbound. This rescue morality spills over into medical care, where our ropes are artificial hearts, our rush is the mobile critical care unit, our teams the transplant services. The imperative to rescue is, undoubtedly, of great moral significance; [...][2]**

Rescue morality recognizes the deep seated desire and, as some have since argued, the perceived duty[3] we have as humans to act when we recognize an endangered life. In fact international public health research experts, Eric Nord, Peter Singer (et.al) argue that this duty is immediate when persons present with serious health conditions.[4]

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[1] Francis I, Evangelii Gaudium [Encyclical Letter on the Proclamation of the Gospel in Today's World] sec. 231-233, accessed January 26, 2015, http://w2.vatican.va/content/francesco/en/apost_exhortations/documents/papa-francesco_esortazione-ap_20131124_evangelii-gaudium.html#Realities_are_more_important_than_ideas

[2] Jonsen, A. R. (1986), "Bentham in a Box: Technology Assessment and Health Care Allocation", Law, Medicine & Health Care 14(3–4), 172–174.

[3] Bochner F, Martin ED, Burgess NG, Somogyi AA & Garry MH 1994, "Controversies in treatment: How can hospitals ration drugs?", British Medical Journal, Vol 308, No 6933, pp901–5, 907–8.

[4] Nord E, Richardson J, Street A, Kuhse H & Singer P 1995b, "Who cares about cost? Does economic analysis impose or reflect social values?" Health Policy, Vol 34, pp79–94.

Few will deny that we as humans experience this compulsion to act. But most of us also grudgingly acknowledge that we could not run our business, public and private services or health care systems while employing this ethic without limits. Furthermore, it is also widely accepted that "spectacle ethics" that turn individual cases into cause célèbre should not dictate public policy. As a result, bioethicists developed a set of criteria determine the necessary and sufficient conditions under which it is appropriate to act under the Rule of Rescue. They include:

1. The victims are visible or easily identifiable;
2. Victims are under the acute threat of impending death;
3. There is a reasonable chance of effective rescue;
4. The risks or costs to the rescuers are acceptable;
5. The circumstances leading to the rescue is exceptional.[5]

Most of us would also agree that the proposed "Right to Try" legislation is appealing in the world of ideas and the realm of rhetoric where personal freedom, personal liberties, self-determination and the pursuit of limitless aspirations are laudable and lofty ideals. But those ideals do not hold up within the constraints of the real world where we must test for the safety and efficacy in our medications and devices (via the FDA), protect patients and the integrity of the human research enterprise, and avoid placing undue burden on manufacturers, investors, scientists, practitioners and providers. In the real world, there are good reasons to think that the criteria above cannot support the "Right to Try" legislation.

The current social climate surrounding the individual cases that motivate this kind of legislation undermines the argument that the legislation meets criteria #1 and #3. Media influences, especially in the United States have turned individual cases into ethical spectacles resulting in policy by exception based on mass appeals and pressures exerted through viral messaging. The people who are identified in this way are generally highlighted for morally irrelevant and inappropriate reasons - because they are young and attractive and not because they are more endangered than other patients.

Equally troubling, the popular framing of the issue characterizes interventions as miraculous and life-saving when there is little to no evidence that the interventions actually result in a good or "hoped for" outcome. Empirical research conducted on visibility demonstrates that our predisposition to support the rescuing of victims in these cases comes not from a conviction based on any evidence of success rates "but rather the impression that a very high percentage of the reference group can be saved (in the extreme case: the one single victim being the reference group).[6] This misconstruing of effects certainly does not argue in favor of our meeting the criterion of reasonable chance of effective rescue. We are not bound, nor should we automatically assume that we ought to provide a treatment that offers no benefit.

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[5] Schöne-Seifert, B, "The 'Rule of Rescue' in Medical Priority Setting: Ethical Plausibilities and Implausibilities" RMM Vol. 0, Perspectives in Moral Science, ed. by M. Baurmann & B. Lahno, 2009, 421–430 accessed at http://www.rmm-journal.de/

[6] Jenni, K. E. and G. Loewenstein (1997), "Explaining the Identifiable Victim Effect",Journal of Risk and Uncertainty 14, 35–57.

But then, proponents may argue, if there *is* some evidence in the first phase of the clinical trial process that the patient may benefit from this treatment, then we should allow that to occur based on the second criteria - the acutely impending death of the patient. Urgency is a given in these instances and experts argue that impending death is a criterion that allows for special consideration in these cases. But we are also obliged to consider the facts before arguing for new legislation to provide that consideration. The FDA, which is responsible for the safety and efficacy of medications prescribed by physicians in the U.S., has updated and expanded its expedited processes for accommodating requests for access to drugs under development called Investigational New Drug (IND) Application.

This process specifically includes provisions for a "Physician Request for an Individual Patient IND under Expanded Access for Non-emergency or Emergency Use." FDA Commissioner Dr. Margaret Hamburg has reported that in FY 2013, the most recent year for which data are available, nearly 100% of all applications submitted were approved (974/977) and many of those requests processed within hours of submission.[7]

Recent efforts within the FDA clearly demonstrate the agency's attention to this issue, especially as scientific discoveries in genetic testing and personalized medicine have progressed. In fact, there are multiple processes that can be sought on behalf of patients in need. These include provisions related to compassionate use and emergency use. In addition, there are special "expanded access" applications for persons living with Cancer and HIV/related diseases. The FDA's responsiveness and compassion in accommodating these applications is clearly evident

FDA has further pledged to continue to streamline its efforts despite its mandate to ensure safety and efficacy. For individual states to adopt legislation that circumvents the process of safety and efficacy places undue burdens on private business and manufacturers. They have repeatedly expressed concerns about their ability to handle and process the applications diverted from the FDA. Besides, they are under no obligation to comply with the patient's request. In addition, some manufacturers have sought to eschew the responsibility of bad outcomes resulting from the desperate attempts by patients who may be imminently dying. Understandably, they do not want adverse events to affect the clinical trial process for larger groups of patients for whom the drugs are intended to eventually benefit.[8]

Ultimately, this is not a "Right to Try" but a "Right to Petition" measure. Drug makers are under no obligation, and they have good reasons not, to divert their private business interests to accommodate desperate appeals by individual patients. The effects of unlimited access to drugs that have only been through Phase One clinical trials cannot be known and subverts the scientific process.

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[7] Hamburg, Margaret. MD "Debate over 'Right to Try' Laws." The Diane Rehm Show, Diane Rehm. WAMU. 88.5 FM, American University Radio, Washington DC, May 27, 2014. Accessed on January 24, 2015 at "http://thedianerehmshow.org/audio/#/shows/2014-05-27/debate-over-right-try-laws/@00:00

[8] Caplan, A, Moch,, H. "Rescue Me: The Challenge Of Compassionate Use In The Social Media Era." Health Affairs Blog, August 27, 2014. Accessed on January 23, 2015 at http://healthaffairs.org/blog/2014/08/27/rescue-me-the-challenge-of-compassionate-use-in-the-social-media-era/

The final criteria of the exceptionality of these instances is indisputable – so. These instances are so rare in fact, that this committee is considering legislation that may, by recent tally based on FDA applications, affect about 5 patients annually in Kansas. Given the substantive concerns raised by manufacturers and drug companies dealing directly with patient requests that could be affected by this legislation, I wonder if it's worth it. Right now the FDA provides all the assurances for the manufacturers that the process has been completed and that the requested intervention (drug or biological) has proven at least in limited instances to be helpful. Given that the system has experienced significant enhancements with recent regulatory accommodations, wouldn't cooperation and collaboration with the FDA be a more feasible and efficient plan than continuing to portray the agency as a barrier and risk diverting patients away from the most capable resource?

In closing, I would like to present one additional concern that I have regarding a suggestion that this legislation should be interpreted as unequivocal in its support of life. This measure's foundational philosophical or ideological argument finds its roots in liberty arguments from an individual rights perspective. I would caution those who claim those interests do not bleed or blur into liberty rights of other sorts to carefully reconsider that position.

This bill champions my right to access treatment, medication or interventions of the kind that may in fact hasten my death because I am trying to prolong my life. This argument is not dissimilar, however, from arguments that patients have used in seeking relief from intolerable suffering, prolonged agony or describing unacceptable future state of health.

Slippery slopes are often indiscernible at the outset. In my estimation this measure deserves serious scrutiny to ensure that we do not mistakenly presume that individual liberties automatically lead to communitarian values and social norms worth protecting.

The sympathetic nature of this proposed legislation makes it universally attractive. Sympathies for those it intends to help are laudable. We should not be naïve however in ignoring the risks associated with the possible impact of its ideological foundation.

Pope Francis' admonition is worthy of note as we examine this aspirational rhetoric from the world of ideas. This measure deserves careful review as it directly and indirectly impacts the lives of vulnerable patients, devoted researchers, and business investors while simultaneously promoting risky treatments that admittedly could cause harm and hasten death.

The agencies that provide for our safety and ensure the efficacy of treatments that are governed by science of medicine are real world. Despite our natural and compulsive need to rescue those who are doomed, this committee and this body retain the responsibility to legislate with prudence and wisdom.

Thank you for the opportunity to share these reflections with you.

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