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**TESTIMONY OF JOHN ADRIAN MULDER, MD, FAAHPM, HMDC**

**Director, Trillium Institute**

**Grand Rapids, MI**

**before the**

**House Committee on Energy and Commerce**

**Subcommittee on Health**

**at a hearing on**

**“COMBATING THE OPIOID CRISIS: HELPING COMMUNITIES  
BALANCE ENFORCEMENT AND PATIENT SAFETY”**

**February 28, 2018**

Chairman Burgess, Ranking Member Green, and Members of the Committee: My name is John Adrian Mulder, MD, FAAHPM, HMDC. I am the Medical Director of the Trillium Institute in Grand Rapids, MI, which provides education on palliative care and end of life issues to medical and lay communities, and navigation services to those dealing with advanced and terminal illnesses. I also serve as Chief Medical Consultant for Hospice and Palliative Care at Faith Hospice, which is part of Holland Home, also located in Grand Rapids. Holland Home is Michigan's largest non-profit provider of senior services and employs over 1,400 people who serve more than 4,000 individuals daily.

Holland Home is an active member of the National Association for Home Care & Hospice (NAHC), the largest national organization representing home health, home care, and hospice organizations of all types; we are also active with the Michigan HomeCare & Hospice Association, which I serve as a board member. Trillium Institute is also a member of the American Academy of Hospice and Palliative Medicine, the National Hospice and Palliative Care Organization, the Center for the Advancement of Palliative Care, and the Coalition to Transform Advanced Care.

As a hospice and palliative care physician who has been caring for patients at the end of life for over 30 years, and on behalf of NAHC, I am honored to present testimony in support of H.R. 5041, The Safe Disposal of Unused Medication Act, which would authorize employees of a hospice program to handle controlled substances in the residence of a deceased hospice patient in order to assist in their disposal. We thank Representative Walberg, as well as Representatives Dingell and Hudson, for their efforts to develop this legislation. I also bring thanks from the Michigan HomeCare & Hospice Association and its strong endorsement for your legislation.

Approximately 98 percent of hospice care days are provided in a patient's place of residence. A high proportion of patients are dispensed medications to address terminal, intractable pain. Most of these drugs are opioids or otherwise classified as controlled substances, and heavily regulated by the federal government. With some frequency, medications that were prescribed for use by a hospice patient will go unused. This can happen for a number of reasons, including when a patient dies or when the hospice initiates medication changes.

In recent years, and particularly since the Drug Enforcement Administration's (DEA's) issuance of final regulations implementing the *Secure and Responsible Drug Disposal Act of 2010*, many questions have arisen regarding the appropriate role of hospice professionals relative to destruction of controlled substances in patient's homes. Under current law, unless a state or locality has enacted legislation that otherwise allows hospices to dispose of unused medications, hospice staff may not handle or destroy such medications in the home. As a result, it is frequently the case that hospice home visiting staff -- who may be the last professional to visit the home in connection with a patient's death -- must leave dangerous medications with a high risk for diversion and misuse by those for whom the drug was never intended in the home environment. These circumstances create a significant challenge for hospice personnel.

Strict adherence to existing federal law means that a hospice may only educate the patient or family in proper disposal methods and/or provide approved mail-back pouches, and supply information about community "drop boxes" or "drug take back" days. This presumes that a willing and able individual with proper authority to dispose of a patient's property is available. This is frequently not the case. Further, not all hospices have access to supplies of mail-back pouches, and public "drop boxes" and "take back" days are few and far between. Some have suggested that hospices call local authorities to come into the home to seize leftover medications. Hospice provider experience indicates that local police and sheriffs' offices are not sufficiently staffed to fulfill this function.

A moderate sized hospice caring for 2,000 patients a year will prescribe approximately 1 million pills per year, the majority of which will be controlled substances. These are typically prescribed in limited quantities – 7-14 day supply at a time – but since it is impossible to predict precisely when a hospice patient will die, there will always be medications left over when death occurs. Similarly, it is not always possible to predict how well a patient will tolerate a medication or dosage, so prescription changes frequently occur during the course of treatment. This yields potentially tens of thousands of pills in need of disposal, and at risk for misuse or diversion.

It should be noted that hospice providers are extremely sensitive to the potential for diversion of medications intended for terminally ill patients. Hospice personnel keep close track of medication supplies in the home and where diversion by family members is suspected the hospice will frequently take steps to address the issue by reducing the amount of medication dispensed, providing lock boxes, alerting the pharmacy of their concern and, in some cases, the local authorities.

Given the growing public health threat posed by widespread misuse of controlled substances, a number of states have enacted or are in the process of developing legislation that would permit hospice organizations to authorize certain home visiting staff to participate in the destruction of unused controlled medications. While these efforts are laudable, there is significant variation among these laws, which ultimately diminishes the ability of the federal government to oversee activities in this area, and does little to ensure that hospices nationwide adhere to a distinct set of standards for destruction of controlled substances in the home.

It is for this reason that we applaud the introduction of H.R. 5041. Under this legislation, Medicare-certified hospice providers may authorize licensed employees that are acting within the scope of their employment to handle controlled substances for the purpose of disposal after the patient has died. In order to be qualified to authorize such destruction, hospices would be required to:

- Have in place written policies and procedures for assisting in the disposal of the controlled substances of the deceased individual
- Have provided a copy of those written policies and procedures to the patient or patient representative and family at the time that the medications are ordered
- Have discussed the policies and procedures with the patient or representative at the time that the medications are ordered and
- Have documented in the patient's clinical record that the written policies and procedures were provided and discussed.

We are gratified to see that the legislation gives hospice providers the option to decide whether or not to authorize employees to assist in destruction of controlled substances in the home. Some hospices are concerned that requiring their staff to assist in the destruction of unused medications could pose a personal risk to those employees or a potential liability risk to the hospice, so we believe it is vital that hospices be given the opportunity to make that choice on behalf of their organizations. We also strongly support the bill's provision that exempts hospice employees from the Drug Enforcement Administration's registration requirements that would otherwise apply. These requirements are complex and would be prohibitively expensive for most community hospices to meet.

We believe H.R. 5041 represents a common-sense, real-world approach to allowing hospice agencies to authorize their personnel to safely handle controlled substances in a patient's residence for the sole purpose of assisting in their proper disposal after a hospice patient's death. It is our belief that the legislation could be further strengthened by extending authority to destroy the medications to instances under which medications for a living patient have been changed (leaving unused medications in the home that could be diverted for misuse) and to specify the disciplines to which the authority would apply (including RNs, LPNs, social workers, physicians, nurse practitioners and physician assistants) so that

there is no confusion over which personnel would be permitted to destroy the medications. We at NAHC, along with our associates at the National Hospice and Palliative Care Organization (NHPCO), have worked collaboratively with the sponsors of H.R. 5041 and we look forward to continuing discussions with you on these issues going forward.

**Additional Issues.**

While I have the opportunity, there are other issues related to prescribing of controlled substances that have emerged in a number of states that have serious implications for the comfort and relief of terminally ill patients and the practice of hospice and palliative medicine. One relates to drug shortages, including supplies of opioids and other pain medications. Throughout the nation, hospices are hearing from their supply houses that they should prepare for widespread shortages as the result of the temporary shutdown of production in Puerto Rico (as the result of Hurricane Maria) and the DEA's reduction in production quotas. We fully appreciate that a vital step in reducing the prevalence of opioid abuse is to reduce overproduction of these medications, thereby limiting the amount that may be available for diversion. However, hospice and hospital providers must have timely and affordable access to medications that are necessary to treat their patients effectively. A hallmark of palliative care is ensuring that we do all that we can to address unnecessary and debilitating pain, and many hospices are fearful that they will be unable to do that in future months.

We would encourage the DEA and the Food and Drug Administration, and other appropriate federal agencies, to ensure that they have a process in place to closely track supply needs, anticipate potential shortages and quickly address them in a way that does not threaten continuity of care or increase the cost of effective care delivery.

Further, many states have enacted, or are developing, legislation that would place additional limitations on prescribing practices for controlled substances. While we agree that these actions are warranted to

help address the growing opioid crisis, some states are placing limitations on the circumstances under which controlled substances can be prescribed without giving consideration to the special needs of terminally ill patients. Of particular concern are provisions that require a prescriber to have a “bona fide” relationship, and more specifically how they define such a relationship. Many of these emerging laws require that a complete history and physical be conducted prior to prescribing a controlled substance, and that the patient again be evaluated before dosing changes are made, or additional medications prescribed.

While there may be clinical circumstances in non-terminal situations in which this may be appropriate, in hospice and palliative care, it is essential that patients have access to medications as quickly as possible in order to control pain and other symptoms that are frequently problematic at the end of life. Moreover, these patients have been heavily engaged in the healthcare system at the time of their hospice admission with complex regimens put in place by their physicians. To require additional hands-on physician intervention to simply maintain their current pain medications is onerous, time consuming, duplicative, and will delay the provision of care. There is no other area of medical practice in which patient care is as carefully scrutinized or monitored. Nurse case managers are in the home at the bedside, communicating with hospice physicians in real time, and facilitating the relationship that effectively manages the plan of care.

In recent months there have been several states in which physicians and hospice providers have had to negotiate with state legislators and regulators to ensure that exceptions to these restrictive laws are enacted to allow effective care of hospice patients. While regulation of prescribing practices is, for the most part, the domain of the state, the issue has emerged with sufficient frequency that I believe it is useful for this committee to be aware of this concern.

In a similar vein, many hospices are finding that in growing numbers community physicians are hesitant to prescribe pain medications for patients with advanced or terminal illness because of the intense

scrutiny that prescribing practices are receiving throughout the Nation. While I believe that these fears may not be well-founded – and clearly, it is not the intention of legislators that hospice patients suffer – this is an issue that is a growing concern in my field. I am very concerned that we could be facing the reality of dying patients being forced into situations of preventable suffering as a result of legislative efforts, that while reasonably conceived, will fail to protect the most vulnerable and prone to suffering. I would also parenthetically note that it is not patients at the end of life, nor hospice physician prescribers, who have influenced the current opioid misuse and addiction issues.

As indicated at the start of this testimony, I am appreciative of the opportunity to discuss these issues with you today. In the course of my palliative work, 15 years ago I was asked to consult with the DEA and the FBI in investigating opioid diversion cases and abuse cases. I have appreciated the opioid challenges that are permeating our communities, and yet understand the need to meet the pain needs of patients at the end of life. I would be pleased to answer any questions that you may have, and, along with representatives of the National Association for Home Care & Hospice (NAHC), welcome the opportunity to serve as a resource to members and staff of the committee.