Senator Kohl's Questions for Michele Leonhart, Nominee for the Administrator of the Drug Enforcement Agency

1. The October 6, 2010 policy allowing a physician to appoint a nurse in a nursing home as his agent to prepare and transmit certain prescriptions to the pharmacy requires that the physician appoint specific individuals within the nursing home to act as his or her agent. We have received feedback from physicians and from nursing homes suggesting that the new policy is unworkable because of both the number of prescribers and staffing patterns within nursing homes. In 1995, DEA's policy (as stated in a letter to the Missouri Board of Pharmacy) actually recommended that an agent designation be to a position, (i.e., licensed nursing staff) rather than to an individual due to "different shifts and staff turnover." Would DEA oppose going back to its position in 1995? If so, please explain your rationale and whether it is based on legal or policy considerations, or both.

   DEA recognizes that the timely ordering and dispensing of controlled substances to patients who reside in LTCFs presents unique challenges. DEA hoped that the policy statement published on October 6, 2010 would alleviate these challenges, and we are concerned if physicians and nursing homes are not finding the policy helpful. The Director of Policy and Advocacy at the American Society of Consultant Pharmacists stated that the policy statement should, "expedite in many cases getting the prescription processed and dispensed by the pharmacist, delivering it to the ultimate user and decreasing the potential for a patient to be in pain or discomfort longer than necessary." And, the Executive Director for the North Dakota Board of Pharmacy also commented on the policy statement by saying that, "This is exactly what we asked DEA to do when we commented during their request for comments on the LTCF issue,…"

   With regard to the above-referenced 1995 letter, that letter dealt only with oral prescriptions for Schedule III and IV controlled substances. In the letter, DEA explained that physicians could designate individuals at LTCFs to act as their agent for purposes of communicating Schedule III and IV oral prescriptions to pharmacies, but discouraged physicians from designating multiple positions or "LTCF staff as a group" as agents. The 1995 letter also suggested that physicians could consider designating a specific position, rather than an individual, as their agent, but DEA issued a subsequent letter in 2002 to the Missouri Department of Health, clarifying that for legal purposes, LTCF nurses could be designated agents of physicians for purposes of communicating Schedule III and IV oral prescriptions only if such nurses were directly responsible to the physician. The 2002 letter is consistent with DEA's October 2010 statement of policy, which outlines the DEA's existing statutory and regulatory requirements as to the proper role of duly authorized agents of individual practitioners with respect to Schedule III and IV controlled substances.

   With respect to Schedule II controlled substances, DEA is interested in working with the Congress to explore the circumstances under which a valid agency

relationship may be established to take into account the uniqueness of long term care settings.

2. Under the October 6 policy, agents may not call in prescriptions for CIIs, even in emergency situations. This means that even if the needed medication is in the nursing home in an emergency kit, the patient will have to wait until the doctor is able to speak directly to the pharmacist and the nurse in the nursing home is able to confirm that this communication has taken place. We understand that this process can delay medication administration in an emergency situation for hours. Why is DEA prohibiting a physician's agent to call in prescriptions for CII's in an emergency situation? Please identify whether the rationale is based upon legal or policy considerations, or both.

   Prohibiting a physician's agent from calling in prescriptions for Schedule II controlled substances is based on statute. The Controlled Substances Act (CSA) <u>requires</u> that schedule II controlled substances be dispensed pursuant to a <u>written</u> prescription except in emergency situations as specified by the Department of Health and Human Services (21 U.S.C. §829(a) & 21 CFR 1306.11 et seq). In qualifying emergency situations, these substances may be dispensed pursuant to a practitioner's oral prescription. (21 CFR 1306.11 et seq).

   DEA recognizes that there may be circumstances unique to the Long Term Care Facility (LTCF) setting that warrant special accommodations. Accordingly, DEA has promulgated many regulations to accommodate the special medical needs of LTCF residents. For example, although schedule II controlled substance prescriptions must be written, a practitioner, *or a practitioner's agent,* may fax a schedule II controlled substance prescription directly to the pharmacy. And, in addition to the emergency kits referenced in your question, DEA registered pharmacies may also install automated dispensing machines in LTCFs. Other DEA regulations may also assist LTCFs to provide necessary controlled substances to their residents, such as the ability of pharmacies to partially fill schedule II controlled substance prescriptions, and the recently promulgated regulations for the use of electronic prescriptions that allow practitioners to electronically transmit prescriptions for controlled substances (regardless of the controlled substance schedule) instantaneously to a pharmacy.

3. As you know, a state-by-state approach to this situation will take years and we don't have that kind of time when nursing home patients are suffering every day. Excluding that option, what will it take for nursing facilities to become DEA registrants?

   Under the Controlled Substances Act (CSA), "[t]he Attorney General shall register practitioners… to dispense… controlled substances… if the applicant is authorized to dispense… controlled substances under the laws of the State in which he practices." 21 U.S.C. § 823(f). Thus, current law provides no latitude to DEA for granting a controlled substance registration to applicants seeking federal authority to handle controlled substances unless those applicants have been authorized in their own state to dispense them.

4. Under what circumstances would DEA be willing to permit dispensing of controlled medications in long-term care facilities based upon a "chart order" rather than a prescription?

   A chart order is a method used in hospitals to authorize the dispensing and administering of controlled substances to a patient, as authorized by a practitioner's order written in a patient's chart or file. This practice is specifically authorized for institutional practitioners such as hospitals. This is permissible under the CSA because in hospitals, *all* of the participants in the prescribing, dispensing, and administering process (the prescribing physician, the dispensing on-site pharmacy, and the administering nurse) are acting collectively as one entity pursuant to the authority of a single DEA registration: the hospital. In other words, because the state has granted the hospital authority to prescribe, administer, and dispense controlled substances to resident patients, DEA may register the hospital as an "institutional practitioner." The hospital's employees/agents can dispense the drugs directly to the patient from the authority of a chart order, provided that all of the hospital personnel are acting within the scope of their professional practice.

   In contrast to a chart order, a prescription is issued by a practitioner under his/her own DEA registration and must contain particular information (including the signature of the prescriber, the date of issuance, the name of the prescribed drug, strength, dosage form, quantity prescribed, and directions for use). Accordingly, outside of the institutional practitioner setting (where a practitioner is acting under the DEA registration of the institution rather that his own DEA registration), chart orders presently cannot substitute for a valid prescription.

   As a result, under current law, unregistered LTCFs may *not* use chart orders to provide controlled substances to residents. This is because some states have *not* granted LTCFs the authority to prescribe, administer, and dispense controlled substances like hospitals; thus, LTCFs cannot register with DEA as institutional practitioners to directly dispense controlled substances to patients. This is in part because most LTCFs do not employ their own physicians and do not have on-site pharmacies under their control. This means that LTCFs cannot preserve the CSA's "closed system of distribution" in the same way as hospitals. Thus, they must rely on valid prescriptions, not merely chart orders, to provide controlled substances to residents.

   We are interested in exploring whether there are circumstances in the LTCF setting in which a doctor's instructions with the required elements in a form similar to a "chart order" could be considered a valid prescription and still ensure that controlled substances are administered safely to patients.

5. Before a registrant appoints an agent, he or she must understand his or her potential liability for acts of the agent under the CSA. What liability does the registrant have for

the agent's acts that were not authorized by the registrant? What are the potential civil and criminal penalties that could be levied against a physician? Please provide examples.

If an agent acts with the express or implied authority of a principal, and that act proves to be a violation of the CSA, the principal/physician would be liable to the same extent as if he or she acted personally. The penalties imposed upon a principal/physician would depend on the conduct and would range from suspension or revocation of the principal's DEA registration to handle controlled substances to imprisonment for an illegal distribution of controlled substances under Title 21.

6. Can you provide the Committee with an assessment of the DEA's national drug take back day on September 25, 2010?

On September 25, 2010, DEA and approximately 3,000 state and local law enforcement agencies participated in the first nation-wide effort to collect unused, unwanted, and expired pharmaceuticals. Approximately 4,000 collection sites were available to the general public in all 50 states. This important health and safety initiative was provided free of charge to the public. Each of the collection sites had a "no questions asked" policy in place to assure the public that they could dispose of their medications without fear of law enforcement action. More than 242,000 pounds of prescription drugs were removed from our nation's homes for safe and proper disposal. DEA received overwhelming positive feed-back from our law enforcement partners and members of the public.

In addition to our state and local law enforcement counterparts, the White House Office of National Drug Control Policy; the Partnership for a Drug-Free America; the International Association of Chiefs of Police; the National Association of Attorneys General; the National Association of Boards of Pharmacy; the Federation of State Medical Boards; and the National District Attorneys Association partnered with DEA in this initiative.

DEA anticipates a second National Take Back Day in the spring of 2011 and will specifically include Long Term Care Facilities in its efforts at that time.

7. Does the Secure and Responsible Drug Disposal Act of 2010, S. 3397, adequately eliminate the legal barriers that have prevented similar initiatives in the past?

DEA would like to thank Congress for its leadership in passing The Secure and Responsible Drug Disposal Act of 2010. As evidenced by the National Take-Back Initiative conducted in September 2010, far too many unwanted or expired medications accumulate in residences throughout the United States. This accumulation of pharmaceuticals is an opportunity for tragedy as medicine cabinets provide unrestricted access to pharmaceuticals that can be diverted for illicit use. This legislation provides DEA with the authority to promulgate implementing regulations that will allow an "ultimate user" and LTCF to transfer controlled substance medication to an authorized entity for destruction, thus eliminating the

legal barriers that have prohibited these initiatives from moving forward in the past.

a. When can we expect these regulations to be issued?

On October 12, the Secure and Responsible Drug Disposal Act of 2010 was signed into law and amended the Controlled Substances Act to provide for ultimate user disposal of controlled substances. DEA has been directed to establish regulations to facilitate this process and will engage in notice and comment rulemaking via Federal Register publication. Interested parties can provide comment to the record that will be considered during finalization of the rule.

DEA is currently working on the draft notice and proposed regulations. We understand the significance of the disposal issues and are working expeditiously on the rulemaking. DEA expects to have the notice completed as soon as possible.

b. Assuming that DEA will work closely with the Attorney General on developing these guidelines, will local law enforcement entities, long-term care facilities and other relevant stakeholders be consulted in the process?

In January 2009, DEA issued an Advance Notice of Proposed Rulemaking (ANPRM) in response to concerns raised by individuals, public and private organizations, the healthcare industry, and the law enforcement community to solicit information on the disposal of controlled substances dispensed to ultimate users, as well as long term care facilities. DEA received more than 150 comments on this issue and will utilize information gained from its ANPRM to address this matter.

DEA will engage all stakeholders regarding this issue as provided by the rulemaking process. In addition to public comment solicited during a published Notice of Proposed Rulemaking, DEA anticipates holding a public meeting in early 2011 to provide an additional avenue to take comment from interested parties.

8. Is DEA coordinating with EPA and other relevant federal agencies in developing guidance for health care facilities on how to address unused drugs?

DEA recognizes that disposal of controlled substances affects not only individual consumers but also health care facilities. DEA registered facilities, such as hospitals, under current law and regulation may utilize the services of a DEA registered reverse distributor to destroy stock controlled substances. Controlled substances dispensed to residents at a Long Term Care Facility, however, belong to the individual, not the facility. DEA will consider varied settings and intends to provide multiple and flexible avenues for proper disposal of controlled substances.

During its rulemaking, DEA will consult with the Environmental Protection Agency and other federal agencies as appropriate concerning this issue.

9. There is high demand for drug take-back programs in my home state of Wisconsin. Prompted by a rise in overdose deaths, the Madison Police Department recently instituted a program to collect unused prescription drugs even though it lacked the resources to do so. Has your agency heard about financial or other challenges from other jurisdictions?

   Many law enforcement agencies have limited staffing and financial resources available to coordinate the collection and disposal of pharmaceuticals. In some cases, the competing interests of enforcement activities may limit an agency's ability to provide sworn officers to staff collection sites or the funding necessary to properly dispose of collected materials. Although law enforcement has been the principal point of contact for controlled substance pharmaceutical collection and disposal programs throughout the country, generally speaking, the resources needed to regularly conduct these initiatives hinder many agencies from pursuing such programs.

10. Will DEA share "best practices" with state and local entities on how to implement successful take-back programs?

    On October 28, DEA participants in the National Take Back Day met at DEA headquarters to discuss the unique challenges and success of this initiative. The meeting provided a forum for a "lessons learned" evaluation regarding planning, organization, and execution. DEA is willing to share its experiences and findings relative to this matter and looks forward to the opportunity to add to the base of knowledge regarding this issue.

    DEA actively endorses state and local take back programs. For approximately three years, DEA has provided written confirmation of specific programs based on written requests by state and local law enforcement agencies through its local Special Agents in Charge.