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October 29, 2010

Via Courier

Office of Deputy Administrator Michele Leonhart
Drug Enforcement Administration
700 Army Navy Drive
Arlington, VA 22202

Dear Acting Administrator Leonhart:

We are writing to convey our concerns with DEA's position regarding the issue of constructive delivery under the Controlled Substances Act (CSA). In all, the organizations signing this letter represent more than 200,000 pharmacists, practitioners or other patient caregivers.

In particular, the agency appears to believe that it is illegal to transfer controlled substances from pharmacies to treating physicians and veterinarians and other home healthcare providers on behalf of their patients for professional safekeeping and before parenteral administration. This appears to contradict statutory language providing for this transfer, as affirmed by the 2007 decision of the U.S. Court of Appeals for the D.C. Circuit in *Wedgewood v. DEA*, 509 F. 3d 541 (D.C. Cir. 2007). DEA's position is also inconsistent with the generally accepted practice in human and veterinary medicine that relies upon constructive transfer of controlled substances to properly treat human and animal patients and prevent diversion.

The existing statute appears to clearly permit a registered practitioner, such as a pharmacist, to dispense a controlled substance through a constructive transfer, such as to the treating physician, veterinarian or licensed practitioner on behalf of the patient. The existing statutory provisions authorize "constructive . . .transfer" – within and even without "an agency relationship" – as a mode of "delivery" from the pharmacy (as "practitioner") to the patient as ("ultimate user") that constitutes an authorized "dispensing." 21 U.S.C. § 802 (8)(10)(21)&(27). The D.C. Circuit affirmed this interpretation in rejecting DEA's position in *Wedgewood*. In addition to the plain language of the statute and the Wedgewood decision several other policy issues argue against DEA's position:

- We have been told that DEA acknowledges and supports the need for legislation authorizing dispensing of intrathecal drugs by pharmacies to treating physicians. However, DEA's current position could result in intrathecal drugs being routed to patients before their physicians or health care professionals can administer them. Proper use of these substances requires the safe injection directly into the fluid surrounding the brain and spinal cord. Obviously, this is not a procedure that can be performed by patients or their caregivers, particularly with substances that often alter a patient's cognitive functioning. Instead, administration must be performed by a physician or licensed healthcare professional as permitted by state practice regulations. Intrathecal drugs are but one subset of sterile, injectable controlled substances that require great care and expertise to be handled and administered safely and effectively. Similar considerations and practices hold for *all* sterile, injectable controlled substances. Nonetheless, DEA's position would appear to prohibit injectable and other controlled substances from being properly transferred to physicians and other licensed healthcare professionals for proper, safe storage and administration.

- Requiring that pharmacies dispense controlled substances only to the patient or household member is at odds with the routine practice of community pharmacies routing controlled substances to such patients by way of physicians or other licensed healthcare professionals.

- DEA's position has potential untoward consequences when it comes to animal patients (who are also governed by the CSA) and veterinary practice. For example, owners of animals can be investment syndicates or individuals residing outside the United States who are unable either legally or logistically to receive and then deliver the controlled substances to the site of administration. This creates an opportunity for diversion (with potential drugs such as anabolic steroids) that can be avoided by sending the medications directly to the clinician who will be administering them. In these instances, the veterinarian who is treating the animal – not the owner or whoever happens to be "in charge of" the stable or farm – is the most responsible and trustworthy party to receive and administer these controlled-substance medications. Similarly, when a veterinarian visits a herd or large zoo, he or she necessarily, prudently brings various medicines to the spot for possible administration without knowing in advance which animal(s) may have immediate need. . DEA's position would hinder the administration of proper care in these circumstances.

We recognize that DEA has adopted its current position with the best of intentions, perceiving it to be part and parcel of combating diversion. Pharmacy groups and the pharmacists we represent are equally committed to combating diversion, ensuring patient safety and maintaining the quality and integrity of the medication from the issuance of prescription to the point of administration. Likewise, we believe Congress had these same patient safety concerns in mind when passing the CSA that incorporated the concept of constructive transfer. In addition, common sense dictates that controlled substances are more safely maintained (and less subject to diversion) when delivered to trained, licensed, regulated prescribers who administer those substances to needy patients.

While no distribution system is perfect, in enacting the statute in question, Congress struck a reasonable balance between diversion control and safely and effectively getting necessary medicines to patients who need them. The _Wedgewood_ decision confirmed that thinking. None of these adverse consequences outlined above arise if DEA recognizes and follows the statute and the _Wedgewood_ decision affirming the provisions of the CSA permitting constructive transfers.

To the extent DEA is concerned about the lack of constraints surrounding constructive transfers to physicians and veterinarians, it is wholly within DEA's power to address those under the existing statute as interpreted in _Wedgewood._ To address its concerns, DEA could easily promulgate rules specifying the circumstances and constraints under which constructive transfer may proceed. Among other factors, DEA could impose appropriate record-keeping requirements commensurate with the goal of guarding against diversion. Promulgating such rules would be in keeping with the DEA's desire to maintain a "closed system" whereby transfer of controlled substances between registrants is regulated and recorded. Indeed, DEA has already undertaken much the same rulemaking exercise in creating an entire "central fill" regime permitting transfers between pharmacies, complete with safeguards specially crafted to address potential diversion concerns. We recommend that the DEA institute a similar policy with respect to "constructive transfers" from pharmacies to physicians and licensed healthcare professionals.

Given the significant problems DEA's position poses for the regulated community, particularly patients with pressing health needs and the professionals who are devoted to serving them, we respectfully ask whether the agency intends to interpret current law regarding constructive transfer in accordance with the decision in _Wedgewood_.

Thank you in advance for your attention to this issue, and we would hope for a prompt resolution so that the current uncertainly as to DEA's intentions on the part of physicians, patients and pharmacists can be resolved promptly. Should you have any questions or need additional information, please contact one of us or Sarah Dodge, Vice President of Government Affairs for the International Academy of Compounding Pharmacists (IACP) at (703) 283-3601.

Sincerely,

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