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Hangover and Hydration Therapy in the Time of Intravenous Drug Shortages: An Ethical Dilemma and a Safety Concern

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The national media have recently put intravenous (IV) hydration therapy and IV vitamins back in the spotlight. NBC's *Today Show* recently aired a story on the opening of a new-age, direct-pay, boutique-style infusion clinic or spa, where customers can go in to receive a variety of on-demand IV cocktails that contain vitamins, trace elements, gastric acid–reducing drugs, or prescription nonsteroidal anti-inflammatory drugs mixed in saline or Lactated Ringer's solution.[1,2] This is a fast booming business with over a dozen new spas and "clinics" opening in major cities such as New York City, Los Angeles, Atlanta, Chicago, Scottsdale, Tampa, and Miami coming this fall.[3-5] In some cities, such as Las Vegas and New Orleans, IV cocktails can be ordered ahead of time and delivered to your hotel room. Customers can also receive "treatment" in a mobile "clinic," which is essentially a bus. The claims for these hydration remedies range from antiaging, improving athletic performance, fighting a cold or flu, to treating a hangover. Under normal circumstances, the commentary section of the *Journal of Parenteral and Enteral Nutrition* (*JPEN*), the American Society for Parenteral and Enteral Nutrition's premier scientific journal of nutrition and metabolic support, is the perfect medium to deliberate about and debate on the scientific merit of IV hydration therapy. But this is no ordinary time.

We are in the middle of a critical IV drug shortage crisis, which the national media have failed to adequately address. As we write this commentary, critical nutrients such as parenteral trace elements, zinc, selenium, copper, multiple vitamin infusion, potassium phosphate, potassium chloride, sodium acetate, sodium phosphate, vitamin K, and cyanocobalamin, many of which are now being given at these hydration centers, are still in severe national shortages.[6] Even Lactated Ringer's solution and sodium chloride 0.9% are in critically short supply to a point that the U.S. Food and Drug Administration (FDA) is exercising its discretion to temporarily allow the importation of saline products from other countries to mitigate this crisis, which itself poses a serious threat to patients.[7,8] Therefore, as journal editors, care providers, researchers, educators, and public policy advocates, we must address this disconnect between free access and the reality of scarce resources. At the present time, the ethical and safety aspects appear to have a more significant implication than the science in this issue.

The Ethics of Prescription Drug Use for Unproven and Unlikely Effective Purposes

Under U.S. law, IV hydration solutions (eg, sodium chloride 0.9%), electrolytes, vitamins, and trace minerals are prescription drugs rather than food, dietary supplements, or supplies. Their use and distribution are regulated by law for medical purposes. The claim of using these *prescription drugs* for unproven purposes, such as hangovers and colds, over established medical needs, such as use in parenteral nutrition (PN) admixtures for patients with short bowel syndrome or other malabsorption syndromes, or in preterm neonates, especially during product shortages, should raise serious concern.

In these clinic or spa businesses, it is unclear who is ultimately responsible for prescribing these medications. Some of these businesses are owned and registered under a licensed medical professional who has prescriptive authority. But it is unclear if the licensed prescriber is actually involved in the assessment or "treatment" of the customers who requested the IV cocktails. Other venues, such as a medical clinic at the

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McCarran Las Vegas International Airport, is a full medical staff urgent care clinic with a licensed pharmacy where hangover therapy is also provided.[9-11] It is appropriate to ask whether this is a proper use of prescription drugs. This is especially concerning when some of the cocktails include prescription drugs such as ketorolac and lidocaine, which can lead to life-threatening adverse events in patients at risk. Some of these IV cocktails even contain substances, such as glutathione, that have never been approved by the FDA as an IV product.

The Ethics of Drug Acquisition and Distribution

With the critical shortages of maintenance IV fluids, electrolytes, and micronutrients, an obvious question is how these boutique infusion clinics and spas procure these substances. Most of these business entities are unwilling to disclose the sources where their products are purchased or prepared.[12] Are these businesses procuring these products through the gray or even black markets, or are they competing with healthcare facilities for the national supply of fluids and nutrients? In fact, over the past 5 years, while many patients were unable to be given some of these critical nutrients, the same nutrients were delivered to customers at these unregulated therapy venues. By doing so, they might have greatly exacerbated the problem with IV drug shortages and possibly depleted our national supply of fluids and nutrients that are much needed by patients who have no other alternative.

Some reports suggest that the suppliers for these boutique clinics are compounding pharmacies or non–U.S.-registered pharmaceutical suppliers.[12] What are the mechanisms to ensure the quality of these compounded products or non–FDA-approved drugs? Legally classified as prescription drugs, IV fluids, electrolytes, vitamins, and micronutrients are regulated under the Prescription Drug Marketing Act of 1987, which was enacted to (a) ensure that drug products purchased by consumers are safe and effective and (b) avoid the unacceptable risk to U.S. consumers from counterfeit, adulterated, misbranded, subpotent, or expired drugs.[13] When compounded or non–FDA-approved products are used, what is the mechanism to safeguard the recipients from receiving products that are subpotent, chemically unstable, physically incompatible, adulterated, misbranded, or even placebos?

If the compounding pharmacies are functioning as outsourcing facilities, are their operations in compliance with state and federal laws and regulations, including USP <797> and the Compounding Quality Act of 2013?[14] Are properly trained or certified personnel involved in the preparation and inspection of their parenteral products prior to delivery? Are the compounded products properly labeled and stored at optimal temperature with a valid use-by date at both the compounding pharmacies and the boutique clinics? These are serious issues that must be addressed so that another outbreak of diseases due to product contamination, similar to the fungal meningitis outbreak in Massachusetts 2 years ago that led to more than 60 deaths, will not be repeated.[15]

We must keep in mind that although this business model is relatively new, the use of vitamin/mineral-fortified IV fluids for nonessential purposes continues amid the ongoing national IV drug shortages. We continue to hear reports about how IV micronutrients, such as Myer's Cocktail and other IV vitamin therapy regimens (most containing high doses of ascorbic acid and zinc), are administered to many professional athletes and celebrities on a regular basis, while practitioners are scrambling to find intermittent supplies for PN-dependent patients.[12,16] At the same time, more reports of patients developing clinical micronutrient deficiencies associated with IV drug shortages have been published in the past 2 years.[17-22] It is unclear how many and how often these businesses compete with hospitals, medical clinics, and home infusion companies for the same distributors in ordering and stockpiling these FDA-approved prescription medications. With the continued challenge of IV fluid, electrolyte, and micronutrient shortages we are facing in patient care, there are still no rules, regulations, or even incentives for putting patients' benefits ahead of business interests and corporate profits. It is unfortunate that the law to allow access to affordable care has been passed but the resource to deliver the most basic level of care, such as an IV saline solution with potassium, cannot be guaranteed in patients with the most need.

Additional Concerns for Non–FDA-Approved Products

If the supply chain for these practices is not in direct competition with the national drug supply for patients, further assessment of their supply sources and practice should be conducted. The suppliers for these businesses should be disclosed. Customers should be followed up for any adverse events, as well as complications related to their infusions, and visits to the emergency department or urgent care clinic should be reported. After all, IV infusion therapy is an established medical procedure with designated *Current Procedural Terminology* (*CPT*) codes. All the recipients of these IV drugs should therefore be entitled to the same level of care and scrutiny for safety provided by their providers.

With proper legislation and monitoring, it is possible that some of these business practices may become partners of healthcare researchers in resolving the IV drug shortage crisis. We can establish minimum standards for safe practices with regard to staffing, drug preparation and administration, and follow-up care in these venues. Those who meet the minimum standards may become licensed facilities, where safety data related to the non–FDA-approved products will be collected and evaluated. The sources of the products will be tracked and routine testing for product consistency will be performed. Agencies and researchers should be given an open source to track these data. This may potentially help the FDA identify and prioritize additional products that can be further reviewed for approval or compounding pharmacies that may be certified to supply a limited number of products locally for patients.

An Issue Close to Home

With the increased access to these business entities, the concerns raised above are not hypothetical and may have already hit home. Consider that one of our PN-dependent patients has utilized an IV boutique clinic for his vitamins and trace elements because the home infusion company is in short supply. Was his IV site manipulated by a trained healthcare provider? Was proper aseptic technique used? What did the patient actually receive? Did the product contain contaminants or other impurities? Were the specific ingredients infused contraindicated in this patient? What if your patient has already developed symptoms related to micronutrient deficiency and wants your advice? Would you take a chance? Would you be able to convince your patient to not take a chance? These are very challenging ethical and safety issues that cannot be addressed without legislative changes and collaboration among individuals with different interests.

In this long-running drug shortage crisis with no apparent long-term resolution, boutique-style IV hydration therapy is an area we can no longer ignore because this business practice has an inseparable impact on IV drug shortage. Instead of viewing the business as villains, we may, with increased transparency and disclosure, legislative changes, and government oversight, find a new partner to take us a step closer in solving our complex problems. We urge the FDA, national legislators, and the business representatives to act swiftly.

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