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A LAW FIRM

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Licensed in the District of Columbia

February 13, 2020

Ms. Rachel Brand
Executive Vice President of
Global Governance and
Chief Legal Officer
Walmart Stores, Inc.
702 SW 8th Street
Bentonville, AR 72716 ***Via Certified Mail, Return Receipt Requested***

Ms. Nuala O'Connor
Senior Vice President and
Chief Counsel, Digital Citizenship
Walmart Stores, Inc.
702 SW 8th Street
Bentonville, AR 72716 ***Via Certified Mail, Return Receipt Requested***

Re: Prohibited Sale of Prescription Devices in North Dakota

Dear Ms. Brand and Ms. O'Connor:

Our firm represents the American Association of Homecare (AAHomecare), the national trade association for manufacturers and providers of durable medical equipment, orthotics, prosthetics, and supplies. AAHomecare has reason to believe that Walmart, through its electronic commerce (e-commerce) platform Walmart.com, is facilitating the sale and delivery of certain prescription devices directly to purchasers in, at least, the state of North Dakota contrary to federal and state law. For the reasons stated below, AAHomecare demands that Walmart cease such sales immediately.

The use of Walmart's e-commerce platform to sell prescription devices in North Dakota violates both federal and state law.

AAHomecare has received information that, in at least one instance, a resident of North Dakota has been able to order through Walmart.com a continuous positive airway pressure (CPAP) medical device from a third-party seller that is not authorized to sell regulated or

restricted medical products.[1] We understand that the CPAP was delivered to the individual's home. Further, we understand that neither Walmart nor the third-party seller made any attempts to request evidence of a prescription for the CPAP or to provide any technical assistance in operating the device.

Federal law prohibits the sale of CPAPs without a prescription. To be legally marketed, a medical device must be cleared and approved by the Food and Drug Administration (FDA)[2] unless expressly exempted by the FDA.[3] The FDA has classified CPAP devices as "Class II" devices because they pose certain safety risks and, therefore, are subject to "special controls."[3] Put another way, the FDA has cleared CPAP devices for sales and marketing for prescription use only.[4]

The sale and distribution of CPAP devices as described above are also precluded under North Dakota law. North Dakota requires a "Durable Medical Equipment Retailer" license for the sale of durable medical equipment (DME), including CPAPs, that are sold or delivered directly to the consumer.[5] Moreover, for DME requiring a prescription, such as CPAPs, the state law requires that the DME retailer maintain documentation of the "original prescription … ."[6] Finally, the law requires that the DME retailer employ or contract with an in-state licensed health care professional (HCP) to prescribe or administer the DME.[7]

It does not appear that the CPAP sale described above was in compliance with federal and state law requirements. First, there is no indication that the third-party seller held the required DME retailer license. Second, even assuming that the seller was properly licensed, it apparently did not require evidence of a valid prescription. Finally, information received by

[1] According to information received by AAHomecare, the seller is the Great Sleep Store and the name of the product is Philips Dream Station.

[2] Under federal law, a medical device is defined as "an instrument, apparatus, implement, machine which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease or intended to affect the structure or any function of the body." 21 U.S.C.§ 321(h).

[3] 21 C.F.R. § 868 5895 (classifying CPAPs as Class II devices)

[4] In their 510(k) submissions to the FDA, manufacturers must demonstrate substantial equivalence to a predicate device already in the market. Substantial equivalence requires, among other things, that the new device have the same intended use as the predicate device. Legally marketed CPAPs are intended for prescription use only. A new CPAP device that relies on a legally marketed device as its predicate to obtain FDA clearance must also be for prescription use only unless it can show the FDA that it is safe for use as an over-the-counter device.

[5] North Dakota law defines "durable medical equipment" as "medical devices, equipment, or supplies that may be used in the residence, including … continuous positive airway pressure (CPAP) devices … ." *See* N.D. Cent. Code § 43-15.3-01 (2016); N.D. Cent. Code at § 43-15.3-11.

[6] *Id.* at 43-15.3-11(1)(b).

[7] *Id.* at 43-15.3-11(1)(a).

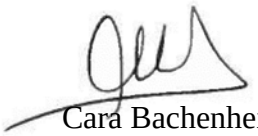
AAHomecare indicates that, instead of providing or offering any technical assistance by an HCP, the third-party seller delivered the device with instructions for self-use.[8]

North Dakota is but one example of many states that have similar restrictions on how an entity can sell CPAP devices to individuals in those states.

In sum, the sale of CPAP devices to purchasers in North Dakota, and likely to purchasers in other states, through Walmart.com in which prescription and licensure requirements are not met is in violation of federal and state laws. AAHomecare demands that Walmart take action to ensure that all future sales comply with federal and state law. Your response to this letter is requested by no later than February 21, 2020.

Thank you for your attention to the above.

Sincerely,



Cara Bachenheimer

jt
c: American Association of Homecare – via email

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[8] Failure to adhere to the above requirements could result in revocation, suspension, or limitation of the license in question, the assessment of civil monetary penalties not exceeding $10,000 (*id.* at 43-15.3-09(1)) and/or a Class C felony charge. *Id.* at 43-15.3-09(6)-(7).