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Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services, Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

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Dear Commissioner:

CITIZEN PETITION

This petition is submitted pursuant to 21 C.F.R. § 10.30. This petition requests that the Commissioner of Food and Drugs place CPAP Machines Over the Counter.

A. ACTION REQUESTED

For the reasons discussed in Section B, this petition requests the Commissioner to do the following:

Make CPAP machines available without prescription. A CPAP (Continuous Positive Airway Pressure) machine is a medical device used primarily to treat obstructive sleep apnea (OSA) and other sleep-related breathing disorders. It delivers a continuous flow of pressurized air to the airway, helping to keep it open during sleep and preventing episodes of breathing pauses or interruptions.

Require that sellers of CPAP machines provide instruction manuals written at the 6th grade level of reading ability and illustrations of the set up.

Here's how a typical CPAP machine works:

Air Pump: The CPAP machine contains a motorized air pump that generates a continuous stream of air at a prescribed pressure setting. The pressure is determined based on the severity of the individual's sleep apnea. Typically it is titrated during a sleep study or under the guidance of a sleep specialist. Some machines continually titrate the air pressure based on resistance.

Tubing: The air from the CPAP machine is delivered to the user's airway through a flexible tube. This tubing connects the machine to the mask worn by the user during sleep.

Mask: The mask is an essential component of the CPAP system, as it delivers the pressurized air

FDA Citizen Petition Place CPAP Machines Over the Counter

to the user's airway. There are several types of masks available, including nasal masks, nasal pillows, and full-face masks. The choice of mask depends on factors such as comfort, breathing patterns, and individual preferences.

Humidifier (Optional): Some CPAP machines come with an integrated humidifier or have a humidifier attachment. The humidifier adds moisture to the pressurized air, which can help alleviate dryness and irritation in the airway and nasal passages.

Filters: CPAP machines typically contain filters that help purify the air being delivered to the user's airway. These filters help remove dust, allergens, and other particles from the air, ensuring clean and breathable air during sleep.

When a person with sleep apnea uses a CPAP machine during sleep, the continuous flow of pressurized air acts as a splint to keep the airway open. This prevents the collapse of soft tissues in the throat and tongue that can lead to obstructive sleep apnea episodes. By maintaining an open airway, CPAP therapy helps improve breathing patterns during sleep, reduce snoring, alleviate daytime sleepiness, and improve overall sleep quality. This makes sleep refreshing, and promotes alertness throughout the waking hours of the next day.

B. STATEMENT OF GROUNDS

Motivation for this Petition

The current requirement of a prescription for a CPAP machine to be purchased results in high costs of \$500 to \$1000. Insurance companies place many obstacles in obtaining them. The FDA's obstruction of the availability results in 80% of apnea patients going undiagnosed. The cost in 2015 Dollars has been estimated to be \$150 billion, in crashes, low productivity, extreme health consequences (<https://aasm.org/resources/pdf/sleep-apnea-economic-crisis.pdf>). Apnea results in daytime sleepiness. Daytime sleepiness causes the same impairment as legal alcohol intoxication (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1739867/pdf/v057p00649.pdf>). The prevalence of untreated sleep apnea is 25 million people from the teens to the elder years. There is no way the nearly worthless, and intentionally obstructionist system under current FDA oversight can accommodate that number. The FDA is just rent seeking professionals that knowingly kill thousands to protect their turf.

The result of CPAP machines availability without prescription will be an immediate increase in competition, and huge drops in prices. The same happened when hearing aids were made available over the counter, with up to 90% reductions in prices. Final Rule at (<https://www.govinfo.gov/content/pkg/FR-2022-08-17/pdf/2022-17230.pdf>). The cost went from \$8000 to \$963 at Costco today, in less than one year.

Self diagnosis is possible. Nothing is more reliable than reports of people who sleep with the person. If the spouse reports pauses in breathing but a polysomnography test is negative, the

FDA Citizen Petition Place CPAP Machines Over the Counter

spouse must be believed. The sleep test measures the breathing of a single night. The report of the spouse reports on breathing over an extended period of time.

Accessibility: Some individuals may have difficulty obtaining a prescription for a CPAP machine due to various factors such as lack of access to healthcare, financial constraints, or delays in scheduling appointments with healthcare providers. Providing CPAP machines without a prescription could increase accessibility for these individuals, allowing them to address their sleep apnea symptoms more promptly.

Self-diagnosis: Some individuals may have already been diagnosed with sleep apnea in the past and are familiar with their condition. Allowing them to obtain cheap CPAP machines without a prescription may empower them to take control of their treatment without the need for additional medical consultations.

Unmet Healthcare Needs: In regions or communities where access to healthcare is limited, providing CPAP machines without a prescription could help address unmet needs for individuals with sleep apnea who may otherwise go untreated. This could potentially reduce the risk of complications associated with untreated sleep apnea, such as cardiovascular problems and daytime sleepiness. "Racial Disparities in Surgical Treatment of Obstructive Sleep Apnea: A National Study of 500,792 Individuals" by K. B. Smith et al., published in 2022. This study found significant racial disparities in the surgical treatment of obstructive sleep apnea, with Black race being independently associated with a decreased rate of surgery for the condition. The study analyzed data from Optum's deidentified Clinformatics Data Mart database from 2004 to 2018, highlighting the health disparities in the management of sleep apnea among different racial groups in the United States. compared to white individuals, African-Americans are often diagnosed with more severe sleep apnea and use treatment with positive airway pressure devices less, based on their zip code. Additionally, black patients have been found to have more severe obstructive sleep apnea upon clinical presentation, but it's unclear if this reflects differences in symptoms or other standard measures of risk. Furthermore, racial disparities in health outcomes related to healthcare access and economic resources have an enormous impact on public health and social equity, with differences in rates of surgery for obstructive sleep apnea based on race. These disparities highlight the need for increased awareness and equitable treatment for sleep apnea across all racial and ethnic populations.

Education and Awareness: Providing CPAP machines without a prescription could also be an opportunity to educate individuals about sleep apnea and the importance of seeking proper diagnosis and treatment. This could lead to increased awareness and encourage individuals to seek professional medical advice if they suspect they have sleep apnea. An effect we call, This Old House Effect, may result. A show detailing all the steps to replacing a toilet is highly persuasive to hire a plumber. The availability of CPAP may increase the fraction of people with apnea seeking professional evaluation and advice.

FDA Citizen Petition Place CPAP Machines Over the Counter

Why the Current FDA Regulations Must be Changed

CPAP is a fan. It blows air. If the air is too much, and uncomfortable, the patient can turn it down, as if it were a window fan. It should not require long wait times and the costs of a polysomnography. The report of family members has far greater validity than those results. If supported by multiple days of sampling by sleep apps, the diagnosis is firm. The result of a sampling of a single night of polysomnography is not valid when it contradicts those multi-day reports. The result of the current professional rent seeking is Medicaid and Medicare fraud, since current procedures and their costs are not medically necessary.

The current fraudulent situation has hideous consequences. It results in foreseeable mass deaths of victims of accidents caused by sleepiness. These may include many historic catastrophes and their devastating effects.

Treated severe apnea patients have the same mortality as the population. Untreated apnea has a 3.8 rate of mortality between the ages of 30 to 49. These are the ages of greatest productivity and responsibility. Around 6000 people that age die needlessly from stroke or cardio-vascular disease, because of untreated severe apnea. The risk of sudden death is also doubled by untreated severe apnea (<https://newsnetwork.mayoclinic.org/discussion/obstructive-sleep-apnea-raises-risk-of-sudden-cardiac-death-mayo-clinic-finds/>)

Discrimination in medicine is a medical practice that includes both differential treatment on the basis of a protected class (disparate-treatment discrimination) and treatment on the basis of inadequately justified factors that disadvantages a particular group (disparate-impact discrimination). Disparate treatment involves intentional discrimination and is per se unconstitutional. Statistical disparity is sufficient for a legal showing of discrimination. In contrast, a determination as to the legality of disparate-impact discrimination depends upon whether the practice is supported by a sufficiently compelling reason and whether alternative processes exist that would not give rise to disparities. Disparate-impact liability mandates the “removal of artificial, arbitrary, and unnecessary barriers . . .”

Request for Action as Direct Final Rule

FDA slowness needlessly kills thousands of patients a year. Therefore you have 180 days to reply to this petition. If I do not get your reply 180 days from today, I will presume the petition has been denied. I will then seek to enjoin you in a federal lawsuit. I will also try to breach your self dealt and lawless immunity. I will seek damages from the FDA for the untreated sleep apnea and its consequences.

FDA regulations at 21 C.F.R. § 10.40(e)(1) provide that “[t]he requirements of notice and public procedure . . . do not apply . . . [w]hen the Commissioner determines for good cause that they are

FDA Citizen Petition Place CPAP Machines Over the Counter

... unnecessary ...” This FDA exemption mirrors a similar exemption in the Administrative Procedure Act (“APA”).²⁹ When enacting the APA exemption, Congress stated that the “lack of public interest in rule-making warrants an agency to dispense with public procedure.” Here, as there appears to be no question of law or fact in dispute, the Commissioner may dispense with advance notice and opportunity for comment.

C. ENVIRONMENTAL IMPACT

FDA regulations at 21 C.F.R. § 10.30 require Petitioner to prepare an environmental assessment under 21 C.F.R. § 25.40. Accidental environmental disasters caused by sleepiness may drop in frequency if this change is enacted.

Exxon Valdez Oil Spill (1989): This disaster occurred when an oil tanker struck a reef off the coast of Alaska, spilling millions of gallons of crude oil into the sea. The captain, who had reportedly been drinking, left a third mate in charge who was possibly fatigued and not fully licensed to navigate the waters, contributing to the accident.

Chernobyl Nuclear Disaster (1986): Fatigue among the night shift workers who were conducting a poorly designed experiment led to the world's worst nuclear disaster. The tired staff made critical errors, including disabling emergency safety systems, which resulted in an explosion and large-scale release of radioactive material.

Three Mile Island Nuclear Accident (1979): Fatigue and inadequate training were contributing factors in this nuclear power plant accident in Pennsylvania, USA. Sleep-deprived operators failed to correctly diagnose and respond to a malfunction in the plant, leading to a partial meltdown.

Space Shuttle Challenger Disaster (1986): While not directly caused by sleepiness, the decision-making process might have been affected by fatigue. Engineers and NASA officials had been working extensive hours and under immense pressure, which led to poor decision-making and oversight in the face of critical safety concerns.

Texas City Refinery Explosion (2005): Overworked and sleep-deprived operators and supervisors were factors in one of the largest industrial accidents in the U.S. petroleum industry. The BP refinery explosion was due to neglected safety measures and tired staff failing to adhere to protocols.

D. ECONOMIC IMPACT

Pursuant to 21 C.F.R. § 10.30, information under this section is to be submitted only when requested by the Commissioner following review of the petition. Briefly, the greater availability of CPAP machines will result in precipitous drops in costs. The cost may drop to a point of working people no longer needing coverage by insurance companies. The prevention of

FDA Citizen Petition
Place CPAP Machines Over the Counter

accidents, crashes, low productivity, misery, strokes, heart attacks, sudden deaths at night, family disruptions. The value of suffering from these consequences has value way beyond the calculation of \$150 billion in 2015 dollars.

E. CERTIFICATION

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to Petitioner that are unfavorable to the petition.

F. CONCLUSION

For the foregoing reasons, Petitioner requests that this petition be granted and that the Commissioner make CPAP machines available without a prescription.

Disparate impact has been deemed evidence of discrimination by the Supreme Court (Texas Dept. of Housing and Community Affairs v. Inclusive Communities Project, Inc., 576 U.S. 519 (2015)). Racial minorities experience implicit bias in the health care system at the rate of 20% (<https://www.kff.org/report-section/kff-the-undefeated-survey-on-race-and-health-main-findings/#ExecutiveSummary>). Forcing them to seek care when not necessary results in disparate experiences and outcomes by race.

Respectfully submitted,

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