

6



Pharmaceuticals and the Making of Modern Bodies and Rhythms

IN 2005, SEPRACOR LAUNCHED A U.S. ADVERTISING CAMPAIGN in the hundreds of millions of dollars to promote a sleep aid, Lunesta, reportedly spending up to forty-three million dollars in one month. Lunesta was developed as a commercial competitor of extant sleep aids that already had the support of health insurance companies, most of which lacked the wherewithal to commit similar capital investments to advertising. Since most patients require some financial aid in defraying the costs of medical treatment and pharmaceuticals, releasing new drugs, which can be on the market for years before being accepted by medical insurance companies as legitimate treatments, is risky business. In the past, most pharmaceutical companies have released drugs and only after years of little commercial attention—other than through drug representatives, who broker with physicians to prescribe their wares—do they attempt to market their products fully, sometimes depending on a new market to emerge, other times producing a new market for a drug. What changed this dynamic was the success of multiple antidepressants in the early 1990s, followed by the wild success of erectile dysfunction treatments in the late 1990s and the early years of the 2000s, both of which relied heavily on direct-to-consumer marketing, allowed by loosened Food and Drug Administration regulations.

At the beginning of the twenty-first century, pharmaceutical companies, having come to the collective realization that humans sleep a

third of their lives, were primed to turn sleep disorders and deprivation into the next pharmaceutical blockbuster. This resulted in a number of pharmaceuticals that were formally intended for severe sleep disorders, such as narcolepsy, being recast as over-the-counter prescriptions for emergent sleep concerns, like “excessive daytime sleepiness.” One of these drugs was Provigil (modafinil), which is produced and marketed by Cephalon, which hoped to achieve some success with marketing the drug as an over-the-counter, “nonaddictive” stimulant (no claims were made about it being non-habit-forming) for individuals with excessive daytime sleepiness and narcolepsy symptoms. Similarly, Jazz Pharmaceuticals and Orphan Medical transformed sodium oxybate or gamma hydroxybutyrate (GHB, which is known more broadly in American society as a date rape drug) into a benign treatment for narcolepsy, renamed Xyrem. In this chapter, I review the strange histories of these two drugs and their possible futures. They are sympathetic drugs in that both are commonly prescribed to narcoleptics, Xyrem as a sleep-inducing drug that is also known to reduce the number of cataplexy events, and Provigil as a drug to maintain wakefulness in narcoleptics during the day. By using both drugs, narcoleptics are able to produce a facsimile of normal American sleep and wakefulness. I follow this with a discussion of caffeine, addiction, and new chemical forms of life that are predicated on a desire for stimulation, not wholly removed from the medical model of pathology offered by narcoleptics.

Cephalon’s 2004 product monograph for Provigil asserts that the drug is intended “to improve wakefulness in patients with excessive daytime sleepiness associated with narcolepsy, obstructive sleep apnea/hypopnea syndrome (OSAHS), and shift work sleep disorder.” With each of these sleep disorders, individuals complain regularly of sleepiness or fatigue during the day, which has been recast under the umbrella of “excessive daytime sleepiness.” Provigil is justified in the case of narcolepsy and shift work sleep disorder but is questionable in the case of sleep apnea, because once patients become used to their CPAP or BiPAP machines, they often sleep more fully through the night, and complaints of sleepiness during the day are reduced. It should also be noted, however, that because of its declassification as a drug used solely for narcoleptics, Provigil has been reclassified as a medical stimulant and can now be prescribed at the whim of attending physicians for any number of drowsy

conditions, from depression to chronic fatigue syndrome. Additionally, in the case of shift work sleep disorder, Provigil has managed only symptoms rather than causes, since, from its inception, shift work sleep disorder has been recognized as a problem of the workplace and its relation to the sleep patterns of workers or, rather, individual workers' inabilities to cope with the rhythms demanded by work.

Cephalon's strategy has been to elaborate both new needs for the drugs that it produces as well as more comprehensive means to include new disordered sleepers in umbrella diagnoses, such as excessive daytime sleepiness. Throughout the Provigil literature, excessive daytime sleepiness is referred to simply as excessive sleepiness, or ES, subtly broadening the times that people might complain of unwanted or unexpected sleepiness. On its Web site for patients, Cephalon states, "People with excessive sleepiness may feel as if they just don't have the energy to do the things they need to on a daily basis, such as spending time with their family or performing duties at work." Other symptoms included mental tiredness, bodily fatigue, difficulty concentrating or paying attention, and low motivation.¹ One might notice in these symptoms the very conditions of modern life, as well as life as it has been lived for centuries. Who, it is reasonable to ask, is exempt from these symptoms? Who has time and energy to spend with their family and perform duties at work? Americans are increasingly beset by everyday demands during time formerly reserved for family and recreation, meaning that when individuals have time to tend to social life outside work, they are already tired. Those "tired enough" might turn to the powers of Provigil.

To evidence Provigil's life-changing effects, Cephalon's Web site features a number of testimonials from patients, one each from individuals diagnosed with narcolepsy, sleep apnea, and shift work sleep disorder, as well as from a director of a sleep clinic. Each testimonial is relatively interchangeable, in that each describes the life of the individual previous to the medication and the individual's newfound vitality since. The following is Donna's testimony, a pharmacist and narcoleptic "who struggled with ES":

[Before Provigil] My life was uh, basically a non life. It was basically uh working and sleeping—that's all I did. I got up on the morning that I had to work and went to work and barely made it through

Pharmaceuticals

the day and uh, people heard “I’m so tired” come out of my mouth probably about 50 times during the day. . . . [After Provigil] Well, since I’ve started taking Provigil, I don’t have the excessive sleepiness so I’m able to do things like eat healthier instead of fast food all the time cause I’m too tired to cook.

Like the description of excessive sleepiness symptoms, Donna’s description of her life has a certain universality: Could many Americans claim to do much more with their lives than working and sleeping? Moreover, could many Americans claim to have time to cook meals rather than eat fast food all the time? Even for those who could answer positively to these questions, there is always the possibility of having even more time for family and friends, eating, and leisure. Provigil might not be able to increase the amount of time in your life, but it may ensure that you are able to use your time fully. In so doing, Provigil, or the vitality that it provides, might become a habit. This extends beyond the possible chemical addiction that an individual might develop, an addiction that could become another form of life with its own desires, something that Cephalon is aware of but has buried both in the fine print of Provigil’s fact sheet, which is made available to physicians, and in much of the patient literature:

In addition to its wakefulness-promoting effect and increased locomotor activity in animals, in humans, Provigil, produces psychoactive and euphoric effects, alternations in mood, perception, thinking and feeling typical of other [central nervous system] stimulants. . . . Modafinil is reinforcing, as evidenced by its self-administration in monkeys previously trained to self-administer cocaine.²

Individuals may become habituated not only to the energy that the drug provides but also to the neurochemical effects of the drug. Untangling these two effects is impossible: the feelings (“euphoric effects, alternations in mood”) are equally social and chemical, economic and biological, a potent intimate chemistry.

Equally potent is Xyrem, a drug that when taken regularly and for an extended period of time reduces the number of cataplexy events of narcoleptics and consolidates nighttime sleep. As with Provigil, the administration of Xyrem has to be justified by physicians, and, as with Cephalon, Jazz Pharmaceuticals is aware of the broader uses and de-

sires for the drug. The physician's reference guide for Xyrem states, "By impairing primary functions like talking, eating, standing, walking or driving, [cataplexy] can prevent patients from experiencing important activities such as holding a grandchild, interviewing for a job, participating in a meeting, going to a movie, attending a party, or working out at the gym." Although not every American desires each of these events in his or her life, the universality of the events is not unlike those outlined by Cephalon for potential Provigil users. And since cataplexy affects the most basic functions of human social life (talking, eating, standing, walking, driving), what cataplectic would choose to go without the drug? Like any pharmaceutical, however, and as discussed in the Xyrem medication guide, Xyrem has a number of side effects, "including trouble breathing while asleep, confusion, abnormal thinking, depression, and loss of consciousness"; it also promotes enuresis and parasomnias, especially in those who are already predisposed to such sleep-related activities. As reported in Xyrem's expansive literature, about 10 percent of users eventually decide to forgo the drug, its negative side effects outweighing the positive benefits it provides. However, this addresses primarily the physiological side effects, and a drug like Xyrem also involves broader social considerations.

Because of the fraught social landscape that Xyrem exists within, where it is probably used illicitly as often as it's used for narcoleptics, Cephalon adopts a stern approach with patients; recall Martin, who confessed to me that he hid his various prescription medications in a locked safe, although he lived with his parents and kept his narcolepsy largely a secret from his friends. In being prescribed Xyrem, patients are expected to watch an instructional video, ostensibly presenting directions for the preparation of the two nightly doses required for efficacy. The host of the video is a middle-aged white woman with graying hair, whose affect varies between motherly and threatening. She warns the viewer: "Careful adherence to the procedures and precautions presented in this video will ensure that Xyrem will continue to be available to you and patients like you now and in the years to come." In the seven-minute video, nearly half of which belabors the preparation of the nightly doses of the medication (three to nine milligrams of Xyrem with two ounces of water, sealed in childproof containers, placed near the bed), the host makes frequent reference to legal themes:

Pharmaceuticals

When controlled substances are used for medical purposes, they can provide improvements in a person's quality of life, and for the many people with debilitating diseases like yours. However, if these medications are illegally diverted from the legitimate distribution system, the nonmedical use of controlled substances can lead to public health problems. As a controlled medication, if you, with criminal intent, knowingly divert, distribute, or sell Xyrem to others, you'll be subject to criminal prosecution.

Unlike Provigil, for which Cephalon desires an unlimited field of possible prescriptions—hence the company's production of its patent replacement, Nuvigil—Xyrem is constrained by its history of abuse and its persistent potential for use on others against their will. Orphan Medical, the distributor of Xyrem, has had to develop a means to ensure that the potential for Xyrem's illicit uses was curtailed and, to that end, has established a central pharmacy and a tracking system for both patients and prescribers. This fails to account for how patients use the drug between receiving their shipments, but it ensures a chain of accountability. Unless these mechanisms dissolve, it will continue to ensure that the spread of Xyrem use is circumscribed, unless what it can be prescribed for is widened.

Whereas Provigil might allow one's life to be maximized, Xyrem has a constraining effect on patients, in that they need to structure their lives around the dose intakes. Like that of many drugs, the efficacy of Xyrem is reduced by food intake, and patients need to ensure that they have digested their evening meal before taking their first dose at bedtime. More complicated is that patients require two doses of Xyrem for it to be effective through the night. The drug has a short half-life, and the consolidated sleep that it provides for narcoleptics quickly dissipates; to reap further consolidated sleep, patients need to take a second dose of Xyrem in the middle of the night: "The second dose is often necessary for the patient to return to sleep for the second half of the night; however, the need to awaken for a second dose of sodium oxybate is usually not an inconvenience, as patients often awaken spontaneously 2–4 h after the first dose."³ Xyrem both consolidates sleep and reduces the occurrences of cataplexy events; the former effect is spontaneous, the latter only slowly begins to take effect after an individual regularly takes

the drug, sometimes taking up to two months. No one can explain the secondary function of Xyrem.

Provigil and Xyrem are often prescribed together for narcoleptics, because these two drugs combine to treat all of the primary symptoms of the disorder. But bodies tolerate the drugs differently, and while some patients respond well to one of them, at times other drugs are required for the consolidation of sleep or the promotion of wakefulness during the day. And, for some, the benefits of the drugs are outweighed by the negative side effects. Medically, narcolepsy patients who choose to live without drugs are advised that they “should live a regular life, go to bed at the same hour each night, and get up at the same time each morning. Scheduled naps or short naps just before activities demanding a high degree of attention alleviate sleepiness in most patients. The optimal frequency, duration, and time of these naps has to be established.”⁴ Such habitual sleep restriction ensures that sleep is spatiotemporally localized, something that can be guaranteed otherwise only through the use of pharmaceuticals. Without the powers of regulation that pharmaceuticals deploy in the bodies of their consumers, disordered sleepers need to achieve this same regulation through behavioral and habitual means: they need to impose a rhythm, with an “optimal frequency, duration, and time.” If patients fear cataplexy events, they need to regulate their emotional feelings, because cataplexy events are tied to extreme emotions. This very social, very intimate concern is addressed in the product monograph for Xyrem, a publication intended for physicians:

Substantial evidence exists suggesting that, without effective treatment, narcoleptics attempt to manage their cataplexy by controlling or suppressing their emotions (adopting a flat affect) or simply avoiding social or other situations known to precipitate attacks. As a result, narcoleptics may be mislabeled as bored, disinterested or unintelligent.

When narcoleptics choose to circumscribe the use of pharmaceuticals, they are foreclosed not just from normal times of sleep and work but also from emotional investment in social interactions as a whole. To legitimate the use of Xyrem and other narcolepsy drugs, pharmaceutical manufacturers and marketers are behooved to expand the powers of the

Pharmaceuticals

pharmaceutical, bringing to the attention of physicians, patients, and their families the chemical, social, and economic needs of disordered sleepers. The questions of chemical toleration and need are perverted by the presence of the social, because patients are enticed to balance the side effects of drugs with the social effects of spatiotemporal estrangement.

In October 2005, at a weekly staff meeting, Dr. McCoy took the floor, brandishing a new canister of Jolt cola, about a liter in size and shaped like a battery, with a positive and negative charge indicator on it, as well as a charge rating along the side. It was the latest addition to his collection of hypercaffeinated beverages, prominently displayed in the communal workroom, which all of the physicians used on a daily basis. He went on to explain that Jolt was also packaged in a new green canister that boasted the drink's guarana content instead of caffeine, which McCoy explained was a way the manufacturer could market the drink as "natural." Dr. Richards remarked that adolescent and preadolescent caffeine intake had increased exponentially in recent years, and he reminisced that he was old enough to remember when soda was consumed only on holidays, because it was too expensive to drink on a regular basis. Dr. MacTaggart asked about the effectiveness of drinks containing taurine, which Richards explained was only an amino acid; McCoy opined that taurine was just another thing that manufacturers put into products to appeal to extreme sports enthusiasts and those interested in "natural" stimulants. This vignette was a recurring one in the clinic. Whenever McCoy purchased a new hypercaffeinated drink, he brought it to share with the collected staff at lunch. Also, the growing awareness of the amount of caffeine consumed by patients and nonpatients alike often led to group discussions about this behavior and the impacts that it might have upon sleep. One of the persistent precautions among sleep hygiene practices is to "avoid caffeine within four to six hours of bedtime,"⁵ and evidence of contrary uses on the part of individuals inevitably led to discussion. It was not uncommon in the clinic to hear reports of patients who admitted to consuming more than a dozen caffeinated drinks per day. This was corroborated in my conversations with disordered sleepers, who frequently discussed self-medication through overcaffeination, with one individual remarking that she estimated her daily intake of coffee to be about twenty mugs per day, or about five liters. One might rightly

Pharmaceuticals

expect to be unable to fall asleep with so much caffeine consumed in a day, but for most disordered sleepers, the amount of sleep debt was counterbalanced with constant caffeine consumption. When the caffeine is finally removed as a stimulus, as before bedtime, the desire to sleep is exposed. But caffeine is only one of many contemporary sources of chemical stimulation available to the sleepless, most remarkable in that it is licit while many of its chemical brethren are outlawed.

Four months previous to McCoy's show-and-tell, Dr. Connors, a pulmonologist who spent most of his hospital time in the emergency room and intensive care unit, claimed that the staff were increasingly seeing methamphetamine users in the hospital. MacTaggart asked if they were from the city or from rural areas in the surrounding region, in response to which Connors explained that the three methamphetamine users who were currently in intensive care were all from "the community," in reference to the inner city, MCMC being the emergency room of choice for city services. Methamphetamine users ended up in the hospital, ostensibly for treatment, after their behavior provoked police to stop them. This prompted Connors to ask about the toxicity of methamphetamines as compared with coffee. One of the sleep technicians explained that methamphetamine use in his hometown was so rampant that Sudafed was now treated as a prescription drug, because canny users could distill methamphetamine from Sudafed and other common components. The technician went on to explain that kids at school were selling drugs supplied to them by their parents, which had led to a crackdown on pharmacy sales of cold medications. Connors asked why people use methamphetamines at all, since 40 percent of the population already uses caffeine. This sort of misconception of caffeine as on par with illicit drugs of methamphetamine's potency evidences clinical attitudes toward caffeine use: it is addictive and problematic. The reporting sleep technician explained that methamphetamine provides an instant sense of euphoria, unlike coffee, which has to be consumed cup after cup, indexing the difference between the licit and the illicit: the former category being slow and moderate in effect, the latter being risky because of the speed and intensity of its effect. A visiting doctor explained that Red Bull use is similar to methamphetamine use in that it provides an instant rush, which in turn reminded him of the early 1980s, when people were doing "street speed" (high levels of uncut caffeine—two grams), which was a

fad that quickly expired. Dr. Pym happened to have a chart on hand of a methamphetamine user who was going through withdrawal during her sleep study; the chart, Pym said, looked indistinguishable from narcolepsy, with bouts of sleepiness throughout the day and very disrupted sleep. McCoy then told how he had recently been in a skateboard shop and had come across a tee shirt (available in kids' and adults' sizes) that read "feels like the first time" and featured an anime drawing of a vial filled with methamphetamine rocks, in response to which the collected staff expressed dismay.

What is quickly revealed in this conversation is the lack of newness in stimulant use in the United States and the seemingly persistent desire on the part of Americans to be pharmaceutically charged. In light of this, could it be any wonder that Cephalon is pushing for broader applicability of Provigil as a nonaddictive stimulant? Just being awake and alert is sometimes cause enough for the normal sleeper to indulge in chemical stimulation. Disordered sleepers expose how pharmaceutical and chemical stimulants blur in their effects: caffeine promotes wakefulness, while sleep aids induce sleep. Caffeine, modafinil, and amphetamines each act on the body in different ways, producing varied effects, but all promote wakefulness, and what distinguishes them is as much biological as social, as much natural as cultural. Similarly, hypnotics, sedatives, and non-benzodiazepines all produce sleep, albeit in different forms and through different mechanisms. The use of everyday chemicals and medical pharmaceuticals, prescribed or not, is the normal condition of American sleep. Some opt out of this rule, but they are held to the same expectations of sleep and wakefulness, productivity and quiescence, rhythm and order, as those who partake of these chemical forms of life. There is no boundary around the chemical-everyday: contemporary everyday life is as much chemical in its contours as it is social and biological, natural and cultural.

In this context we might rethink the contemporary therapeutic milieu: the lives of disordered sleepers are littered with inopportune eruptions of sleep, accidental but unsurprising sleep, from narcoleptics who nod off when excited to the case of a woman who would fall asleep at parties, be unrousable, and then be taken home by strangers (to their homes, not hers), and find herself waking up on strange couches in strangers' homes. The inappropriately sleepy body disrupts the very conception

of appropriateness and everyday life's rhythms; the disordered sleeper disrupts the spatiotemporal order of everyday life. The regular body is the body that lays the foundation for the everyday. The imposition of inevitability—that the everyday must unfold in particular ways and that all bodies should behave similarly—creates parity among actors, in this case between individuals and society, between one and the masses; it renders them isomorphic and subject to the same rules. In the social formulation of the inevitabilities of American capitalism and expectations of human desire, these isomorphic bodies are rendered congruent in rough fashion and inseparable. In order to achieve this level of parity, all actors, individual and institutional, depend on being rendered abstract, on signification over and against the material, on universality versus the particularity of individual lives. These formulations of desire depend on the relation of the masses versus the individual—of the integral and the everyday. Attributing inevitability and diverting it from the abnormalities and insurances that occur in individuals and institutions produce a logic of equivalence among actors; individuals become like institutions, and institutions like individuals. It is in this realm of equivalence that bodies enter the domain demarcated as biopolitics, for it is only through the discursive construction of the natural (the bodily, the biological) and the social (the cultural, the economic) that our desires are pitted against one another and become subsumed in the projects of integral medicine. Our desire for sleep is accepted as biological and natural, despite its intimate complexities.

An overlooked aspect of biopower is the construction of the inevitable over and above its usual insistence on the production of the normal: if biopower is concerned with conceptualizing the potential of bodies, human and otherwise, then essential to any understanding of the body is what the body *must* do, how regular its behaviors should be, how flexible its potentials are, what its desirous and intimate capacities are. If one is to tackle the concept of inevitability from the perspective of its constructed nature, it becomes simply the by-product of larger biopolitical regimes; the category of the inevitable is produced in the increased control of bodies, a spatiotemporal expectation of normalcy that aligns individual bodies with institutional orders. Control regimes depend upon establishing equivalences among discrete objects, on capturing diverse phenomena through governmental means, and on inducing a desire in

individuals to align their rhythms with what is taken to be inevitable, to be normal. In this case, the inevitable is the consolidated model of nighttime sleep paired with constant vigilance throughout the day.

For each disordered sleeper, normative expectations of the inevitable are put into question, including narcoleptics who spontaneously fall asleep, insomniacs who fail to sleep through the night and insist on naps, irregular sleepers who fail to align their circadian rhythms with dominant spatiotemporal orders. All of them are subject to the designs of control, and some of them strain against the efforts to fully capture them, to move them from the abnormal to the pharmaceutically regularized. As the case of Provigil shows, the diagnosis of new sleep disorders, or rather “waking disorders,” indexes a forthcoming expansion of the field in which such models of subjectivity circulate. This, in turn, induces the very category of the inevitable to change. Early in the twenty-first century, Americans are moving steadily away from the possibility of taking a daytime nap and more deeply into the requirement to remain ever vigilant throughout the day, by chemical means if needed. With the intensifying of the spatiotemporal rhythm of everyday life, bodies are becoming more akin to society: bodies must be able to anticipate change, they must desire new intimacies, and constant alertness means that individuals are prepared whenever they are called upon, by work, family life, schooling, or any other social obligations.

In the course of a few short years, excessive sleepiness may successfully become the new erectile dysfunction, the new depression, if Cephalon and its compatriots in marketing pharmaceuticals throughout American society have their way. It will move from the realm of the undiagnosed to the overdetermined. We will no longer have to depend on one ubiquitous drug, sold only through prescription; sleepiness will be relegated to an over-the-counter, direct-to-consumer diagnosis. As a result, we may no longer accommodate our lifestyles to our desires for sleep; we may no longer simply become sleepy; rather, new desires will be bootstrapped into being, new diagnoses will be made available to patients and physicians alike. Rather than creating more stimulating environments or allowing flexibility for daytime sleep, we may take pharmaceuticals, like caffeine before them, in order to maintain vigilance in increasingly quotidian workspaces and in regimes of increasingly taxing demands on time. Stemming from this will be a tacit acceptance of these banal spaces,

Pharmaceuticals

leading, inevitably, to a spiral into spatiotemporal orderings of everyday life that replace one form of life with another, with intimate obligations controlled by the demands of capitalism. The logic of nature, primordial or modern, is replaced with the logic of the pharmacy and the natures it can produce. The disordered body is more fully controlled through these intimate strategies, producing dependencies that, in turn, help to circulate capital, as coffee, sugar, and tea did before pharmaceuticals. The flexibility of the body and its desire for sleep becomes supplanted by the constructed inevitability of capitalism. In the process, the individual body is replaced by the slumbering masses—populations to be regulated and managed. The necessary politics to contest this biopolitical order realigns the everyday with the manifold capacities of the body, with embracing the multiple desires for sleep, with resisting the imposition of inevitability on the everyday, on work, school, recreation, and family life through the proliferation of desires and intimacies too manifold to be controlled in their entirety.

This page intentionally left blank