

Hermeneutics of Food and Drug Regulatory Policy

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ABSTRACT

In this paper, I examine the philosophical foundations of the regulation of edible things with particular emphasis on interpretations of the ontological relationship between the categories of 'food' and 'drugs.' To illustrate the diversity of possible approaches to the regulation of food and drugs and their correlative ontological commitments, I focus on two different examples: the United States Food and Drug Administration's Dietary Supplement Health and Education Act (DSHEA) and the development of India's Ministry of Ayurveda, Yoga and Naturopathy, Unani, Siddha, and Homeopathy (AYUSH). In my examination of these two regulatory bodies, my goal is not to provide a universal or absolute answer as to how the food-drug relationship *ought* to be interpreted or codified within regulatory policy. Rather, I aim to provide support for the following claims: (1) these regulatory policies are undergirded by philosophical assumptions regarding the ontological relationship between the categories of food and drugs, (2) the regulatory structure of the US Food & Drug Administration rests on a dichotomous interpretation of the food-drug relationship, (3) India's Ministry of AYUSH rests on an interpretation of the food-drug relationship that understands the categories of 'food' and 'drugs' as overlapping with one another, and (4) each of these approaches to the regulation of edible things has unique advantages and disadvantages that ought to be recognized and evaluated in developing and revising policy for the regulation of edible things.

1. Hermeneutics, Ontology, and the Food-Drug Relationship

A core tenet of philosophical hermeneutics is that our experience is always mediated by presuppositions, and always involves interpretation. Thus, it is important that hermeneutic theory be applied to examine a variety of phenomena and modes of understanding. Hermeneutic philosopher Hans-Georg Gadamer observes that "we consider application to be just as integral a

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part of the hermeneutical process as are understanding and interpretation” (2012[1960], p. 307). Such application holds the promise of uncovering the way that particular interpretive processes take place, as well as the development of various presuppositions and how these shape experience. Further, the acknowledgement of interpretation as an ongoing process undergirding and involving experience also makes possible a position of openness toward differing interpretations.

If experience in general is always mediated by presuppositions and involves the aforementioned interpretive process in regards to the hermeneutic circle, then this is also the case regarding (1) our experiences of particular edible things and our categorization of them as food and/or drugs, and (2) our presuppositions regarding the nature of the relationship between the ontological categories of food and drug (as well as the question of whether these are indeed separate or separable categories).

A hermeneutics of edible things acknowledges that we do not have unmediated access to the “reality” or ultimate nature of edible things beyond experience (if there is such a mind-independent dimension of reality). This approach also recognizes the dynamic interplay between our presuppositions regarding the ontological categories under which particular edible things could accurately be subsumed, and our experiences of those particular things. We enter into experiences of edible things (as with all experience) with historically-effected consciousness. In this context, we find ourselves in a given experiential situation where our interpretations of edible things as foods and/or drugs are informed by our prejudices regarding the nature of those categories. In tandem with information that we pick up through practices such as dialogue and research, these experiences can confirm or alter our prejudices, which in turn continue to shape our experiences.

My goal here is not to attempt to perform an exhaustive conceptual analysis of the ontological categories of food and drugs. I’m not trying, in an absolutist sense, to identify the necessary and sufficient conditions for something to accurately count as a food or drug, or to specify the ultimate nature of the relationship between these categories. Instead, I attend to the grounding of the myriad ways that people can and do experience and conceptualize edible things, and the ways that these different conceptions undergird approaches to the regulation of edible things.

Gadamer argues that “[t]he dialectic of experience has its proper fulfillment not in definitive knowledge but in the openness to experience that is made

possible by experience itself” (*Ibid.*, p. 350). Once we grant that experience is mediated and requires interpretation, this allows us to also recognize that our current interpretation is one of many. This is not to say that we must take the view that all interpretations are equally “good” or “valid,” but that we should remain open to other ways of understanding in order to acknowledge, respect, and investigate these as well as to become aware of and cast a critical eye toward our own forms of interpretation. If this is the case in general, then it must also be regarding the regulation of edible things in regards to the categories of food and drugs.

2. The History and Philosophy of United States Food and Drug Regulation

In this section, I provide an overview of the historical development and policies of the United States Food and Drug Administration (FDA) to unearth and examine implicit interpretive modes which influence, and which are influenced by, regulatory decision-making.

The name “Food and Drug Administration” illustrates the importance that people have placed on the relationship between these ontological categories. Even under interpretive modes that see food and drugs as ultimately separate categories of edible things, there is often still an implicit acknowledgment of *some sort* of association between the two. Though we may take the name and the existence of such regulatory agencies for granted, we are still able to raise the questions of *whether* and *why* food and drugs ought to be regulated by the same agency. Importantly, even if there is good reason for this to be the case, it is not *necessary* that regulation occur in this way. Regulatory decision-making does not occur in a vacuum, but always takes place through some interpretive lens, inflected by history while simultaneously influencing current and future interpretations and practices.

Attorney Paul Hyman observes that “the development of food and drug law can be said to have paralleled the development of civilization” (Hyman 2014, p. 20). Regulations focused on protecting citizens from danger and fraud in food consumption, as well as ensuring fair trade practices, can be found at least as far back as the Code of Hammurabi in 18th century (B.C.) Mesopotamia, as well as early laws in China and India. Humanity’s fluctuating interpretations of the food-drug relationship can also be traced through regulatory structures to some degree:

Until relatively recent times, and the development of analytical chemistry and the beginnings of modern medicine, the regulation of food encompassed drugs as well. [...] By the middle of the 19th century, the advance of analytical chemistry and the use of the microscope to analyze foods led at last to broad food and drug laws in Europe and the United States (Hyman 2014, p. 21).

In this way, the emergence of contemporary dichotomous interpretations of the food-drug relationship maps onto the ideologies and technological innovations of modernity.

Part of the dominant scientific ideology is that the world is best and most fundamentally understood by breaking it down into its component parts and analyzing these parts in isolation from one another. This is associated with the dominant reductive ideology in nutritional science (Scrini 2013). The development of modern chemistry has not only been influential in guiding the regulation of food and drugs, but is also correlated with the interpretive shift from overlapping to dichotomous interpretations of the food-drug relationship.

This is not to say that dichotomous interpretations of this relationship were previously non-existent, but that contemporary dichotomous interpretations are often based on an understanding of drugs as substances that are chemically synthesized (albeit from “natural” ingredients such as foods and plants) via explicit and intentional human actions. For example, in 1868 and 1872, Parliament extended England’s Adulteration of Food and Drink Act (originally enacted in 1860) to include medicines (Hyman 2014). This regulatory decision corresponds with the emergence of the 19th-century interpretation of drugs as an ontological category distinct from food. In the United States, food and drug regulation was only carried out at state and municipal levels until Congress enacted the Food and Drugs Act of 1906, largely due to Upton Sinclair and other journalists’ exposure of fraudulence and public safety concerns in these industries.

Section 6 of the 1906 Food and Drug Act defines the regulatory categories of “food” and “drug” in the following ways:

That the term “drug,” as used in this Act, shall include all medicines and preparations recognized in the United States Pharmacopeia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals. The term “food,” as used herein, shall include all articles used for food, drink, confectionery, or condiment by man or other animals, whether simple, mixed, or compound (Food and Drug Act of 1906).

These definitions disclose hints at underlying interpretive modes driving this and related legislation. Further, though other regulatory acts and amendments have been enacted since 1906, these basic definitions continue to be operative amid other revisions and expansions. The distinction between “use” and “intention of use” differs between the definitions of food and drugs. If it is *intended to be used* for curing, mitigation, or prevention of disease, any substance could potentially count and be regulated as a drug. However, preceding this language is an appeal to the authority of the United States Pharmacopeia (USP) and the National Formulary, thus elevating the public health roles of these two indices in determining what does and does not count as a drug, as well as determining the appropriate intent of use for various substances. The definition of “food,” on the other hand, does not include any explicit deference to external authorities, but simply encapsulates any articles *used* as food. While both definitions exhibit a certain degree of circularity (which perhaps cannot be avoided in its entirety), the definition of “food” entails a more egalitarian understanding of *who* gets to decide what counts as a food, as opposed to a drug. These definitions provide a glimpse into a dichotomous interpretive mode where edible things require a special fiat to be properly considered drugs.

3. DSHEA, Dietary Supplements, and Food/Drug Dichotomies

In addition to outlining the history and philosophy of food and drug regulation, as well as the emergence of the modern dichotomous interpretation of food and drugs, it is also worth discussing a recent regulatory implication rooted in the codification of this interpretation. As noted above, substances considered to be drugs involve greater deference to regulatory bodies than do substances considered to be foods. The FDA renders determinations of substances as members of one or the other category based in part on claims made regarding the uses of those products. Since the passage of the Food and Drug Act of 1906, and throughout the 20th century, if manufacturers of edible things claimed that their product was useful or “good” for treating diseases, the FDA interpreted these claims as alleging drug-like benefits. The FDA would then regulate those products as drugs, requiring evidence for the above claims based on controlled clinical trials (Nestle 2013). In practice, this policy aimed to protect consumers by preventing manufacturers from making unfounded claims about the alleged therapeutic uses of their products.

Until the end of the 20th century, a consequence of this policy had been that dietary supplements could be sold and regulated as food substances, but with strict federal control preventing manufacturers from making and advertising the aforementioned “drug-like” claims which would then legally obligate them to produce supporting data. However, after prolonged political pressure from the supplement industry, Congress passed the Dietary Supplement Health and Education Act of 1994 (DSHEA), leading to what food studies scholar Marion Nestle refers to as “the present anarchy in the dietary supplement marketplace” (*Ibid.*, p. 223). Appealing to the widespread use of supplements by over half of adult U.S. citizens, the industry pushed for this legislature in an effort to limit the power of the FDA in regulating their products. DSHEA allows for dietary supplement companies to make *crypto*-drug claims without having to have their products legally recognized or regulated as drugs:

With DSHEA, the supplement industry won the right to state that an untested product promotes healthful cholesterol levels, but not that it lowers cholesterol; that it supports regularity, but not that it relieves constipation; that it maintains healthy joints, but not that it reduces symptoms of arthritis. [...] In advertisements, however, marketers are permitted to make much more blatant statements about health benefits, just as long as they can produce a supporting study if anyone asks for it (*Ibid.*, pp. 229-230).

According to the American Cancer Society, “dietary supplements are treated more like special foods” when it comes to the FDA’s regulatory standards (2015). While the FDA considers new drugs to be unsafe until they are proven safe, dietary supplements are considered safe until proven unsafe (*Ibid.*).

Nestle teases out the two competing belief systems undergirding the different regulatory perspectives in the DSHEA controversy. In what she refers to as the “two-culture problem,” Nestle denotes the central characteristics of the “science-based” belief system which ideally *should* undergird the FDA’s policies—where the safety and effectiveness of products is demonstrated with mainstream scientific data—and contrasts this with the “belief-based” approach endorsed by the supplements agency, where consumers should have the right to make their own decisions about product efficacy and value based on personal beliefs:

People who hold belief-based attitudes tend to view supplements as natural products that (1) promote health, (2) correct dietary deficiencies due, for example, to poor eating habits, depletion of nutrients from soil, pollution, stress, or aging, and (3) are far less likely than FDA-approved drugs to be

harmful. In contrast, people who adopt science-based approaches tend to believe that most dietary supplements are of questionable content and safety and that any health benefits claimed are largely unproven. For the most part, the rationale for both sets of views is demonstrably factual; it is only the *interpretation* that differs (*Ibid.*, p. 231).

In a subtle hermeneutic move, Nestle emphasizes the role that differing interpretive modes play in shaping perspectives on substance regulation. While I agree with her assessment of the importance of interpretation in the debate over regulation of dietary supplements, as well as her characterization of science-based and belief-based attitudes, it is also important to emphasize the important role that interpretations of the food-drug relationship play within this controversy. The dichotomous structuring of the FDA's regulatory system—such that “food” and “drugs” are treated as separate ontological categories—importantly allows for classificatory ease, as well as further protection of the public from quackery and deception, such as the presentation of an edible thing as both a food and a drug for the sake of profit.

At the same time, this structuring opened the possibility for regulatory challenges regarding substances such as supplements. The passage of DSHEA actualized this possibility to the benefit of the supplement industry. DSHEA led to the FDA considering dietary supplements as a “special” subcategory of food, rather than, for instance, its own “in-between” category of edible thing with its own regulatory schema. This effectively allowed supplement companies to make a variety of unverified health-related claims if accompanied by a recognition that those statements have not been evaluated by the FDA. While, in one sense, this allows consumers to make their own belief-based decisions about a supplement's efficacy and value, this move ultimately strips away the grounding for informed decision-making while leaving no government-sanctioned standard in its place.

4. Interpretations of Food and Drugs as Overlapping Categories in Traditional Medicine

In the next two sections, I look at a scenario that parallels my above discussion of the United States FDA regarding the emergence of India's Ministry of AYUSH and the legal treatment of food and drugs as overlapping ontological categories. Even a brief study of Ayurvedic medicine indicates that Indians have long interpreted a number of edible things as both food and medicine. This interpretive mode is still pervasive, even given the rise of dichotomous food-

drug interpretations in allopathic medicine and the development of synthetic drugs. In a 2013 study of views on health among Indians in the US, the authors found that the “medicinal value of spices was overwhelmingly agreed upon by respondents. The unique combinations of spices and herbs that are used skillfully in cooking Indian food originate from the health-oriented properties that each is considered to possess within a ‘native’ system of illness and medicine” (Mukherjea et al. 2013, p. 321). The acceptance of herbs, spices, and other foodstuffs as medicine is also accompanied by the use of many varieties of plants. It has been estimated that 1200-1800 plants are used in Ayurveda alone (Sen and Chakraborty 2017). This figure does not consider other traditional forms of Indian medicine such as Suddha, Unani, and Amchi, each of which also incorporates hundreds of plants into its respective practices (*Ibid.*).

In order to avoid reifying a western/non-western binary regarding how people interpret the relationship between the categories of food and drugs, it is worth noting that the two food-drug interpretations discussed here do not map onto geographical distance or geopolitical boundaries. For example, many traditional knowledge systems in what is now the United States also evince an understanding of the categories of food and drugs/medicines as overlapping with one another. In her book *Recovering the Sacred: The Power of Naming and Claiming*, Ojibwe environmentalist and writer Winona LaDuke states: “The recovery of the people is tied to the recovery of food, since food itself is medicine, not only for the body, but for the soul, and for the spiritual connection to history, ancestors, and the land” (LaDuke 2005, p. 210). LaDuke’s view entails a recognition of food’s potential to be both healing medicine and harmful drug. Specifically, LaDuke connects the denial of traditional food access and federal allotment of calorie-dense but unhealthy “commodity” foods with the rise of poor individual and group health in Indigenous communities:

As colonizers drove Indigenous peoples from our territories, we were cut off from access to traditional foods. Starvation and disease became rampant. The forced reliance on inadequate government rations [...] only changed the starvation from quick and obvious to hidden and slow. Today, Indigenous communities are recovering agricultural traditions linking past to present and future—and, in the process, restoring spiritual practices related to foods, while strengthening community health and self-determination (*Ibid.*, p. 191).

LaDuke not only argues that poor health proliferates in the absence of traditional Indigenous foods, but also that restored health proliferates in the presence of those foods.

While one would be hard-pressed to find a medical system, traditional or otherwise, that completely neglects the possible role of food in health and well-being, some systems clearly take a stronger perspective on this role than others, as illustrated in the general lack of nutritional education in medical schools (Crowley et al., 2019). Contrary to this perspective, the emphasis on food as medicine in traditional knowledge systems has trickled down into lay populations as well as those with explicit medical training. In a study on Indian views of diet and health in the United States, one participant expressed her interpretation of the food-drug relationship in the following way:

All spices have some medicinal value. Some things are known as grandmother's spices. If you know about spices from your grandmother and mother, you can avoid going to the doctor. I feel you have to watch and observe yourself. And make use of the spices and you will feel better (Mukherjea et al. 2013, p. 321).

This provides a brief glimpse into the cultural, intergenerational transmission of nutritional and medical knowledge, as well as an accompanying interpretation of the food-drug relationship where these categories are understood as overlapping. The interviewee not only interprets spices as medicinal, but goes so far as to suggest that knowledge of the medicinal properties of spices can actually be implemented *in place* of seeking the care and counsel of a physician. Such a view goes well beyond allopathic medicine's uneasy recognition of the potential value of some "alternative" treatments as *complements* to its own standard practices (at best), wherein a dichotomous interpretation of the food-drug relationship is still centered as the default approach to prevention, healing, and health. Getting clear on this contrast is key in better understanding the context within which the Ministry of AYUSH emerged, as well as its interpretive underpinnings.

5. The Ministry of AYUSH and the Food-Drug Relationship

The influence of Ayurveda and other interpretations of the food-drug relationship that understand these categories as overlapping has not rendered traditional Indian medicine immune to impacts from shifting dominant narratives, and many of these impacts have occurred by way of imperialism. Pharmacy scholars Saikat Sen and Raja Chakraborty observe that

Since ancient times, Indian society has depended on traditional medicinal systems practiced here. The introduction of allopathic drugs during the British era, and the neglect of Indian traditional medicine by British rule, are

responsible for significant erosion of Indian traditional medicine. High scientific progress in allopathic medicine and modern facilities also resists the growth of traditional medicine (Sen and Chakraborty 2017, p. 235).

Allopathic medicine has led to numerous important breakthroughs in medical treatment. However, its prevalence has also led to the delegitimation of traditional knowledge systems. In the late 20th and early 21st centuries, the Indian government made great strides in moving from a dichotomous approach that entails the domination of some knowledge systems and the subordination of others, towards a more integrative and pluralist approach to medical practice. At the same time, the novelty of this approach also poses interesting regulatory challenges that underscore the importance of a philosophical examination of food-drug interpretations.

While India began developing and implementing national policies on medicine regulation in the Drug and Cosmetic Act of 1940, the Indian government did not officially recognize and account for traditional medicine in this act until 1959. In the 1960s, the government introduced new revisions of the act specifically focused on Ayurveda, Siddha, and Unani drugs (*Ibid.*). After the formation of various committees dedicated to developing, clarifying and evaluating different traditional forms of Indian medicine in the latter half of the 20th century, the Department of Indian Systems of Medicine and Homeopathy was established as a separate department under the Ministry of Health and Family Welfare. After further expansion and modification in the early 2000s, the Indian government created a separate ministry for traditional Indian systems of medicine (ISM)—the Ministry of Ayurveda, Yoga and Naturopathy, Unani, Siddha, and Homeopathy (AYUSH)—in 2014 (Ministry of AYUSH 2017).

The existence of a separate government ministry specifically dedicated to ISM demonstrates a marked shift in emphasis from the comparative lack of recognition of ISM in the original Drug and Cosmetic Act of 1940. While part of the motivation for the Ministry of AYUSH is to take seriously the potential efficacy of multiple modes of medical knowledge, another motivation lies in growing concern for rural populations with limited or no access to allopathic medicine and physicians. As reported in 2015, India's ratio of allopathic doctors to patients is 1:1700, while the inclusion of AYUSH practitioners changes this ratio to 1:800. AYUSH practitioners are also more readily available in rural areas compared with modern allopathic doctors (Roy 2015).

Thus, the governmental rationale behind the Ministry of AYUSH appears directed toward the promotion of citizen access to quality healthcare through the

institutional legitimation of traditional medical epistemologies—epistemologies embedded in interpretations that understand the ontological categories of ‘food’ and ‘drugs’ as overlapping with one another. Moving beyond the dichotomous understanding of allopathic/traditional medicine, the Ministry of AYUSH has also played a vital role in the recent integration of traditional medicine within “regular” healthcare service. This integration has manifested in several ways, including the appointment of AYUSH doctors and healthcare professionals in primary health care centers, the availability of traditional medicine at these centers, and the inclusion of AYUSH in India’s National Reproductive & Child Health Programme (Sen and Chakraborty 2017).

The Ministry of AYUSH does not shy away from or obscure its endorsement of “food as medicine” as a legitimate interpretive mode. Consider, for instance, the Ministry’s discussion of naturopathic diet therapy, and the distinctions among “eliminative diets,” “soothing diets,” and “constructive diets”:

Being alkaline, these diets help in improving health, purifying the body and rendering it immune to disease. To this end, a proper combination of food is necessary. Our diet should consist of 20% acidic and 80% alkaline food for maintaining health. A balanced food is a must for any individual seeking good health. Food is regarded as Medicine in Naturopathy (Ministry of AYUSH 2016).

In this way, the emergence and development of the Ministry of AYUSH reflects a long-standing emphasis on pluralism as a core, unifying feature of Indian identity. There are two levels at which Indian pluralism shapes, and is shaped by, interpretations of the food-drug relationship. At one level, a pluralist view of reality allows for the possibility that a given edible thing does not have to be *either* a food or drug, that it can be a member of multiple ontological categories at once, and that these ontological categories need not, at least by default, be interpreted as mutually exclusive. Further, this view creates space for an interpretation of food-drugs in both the healing/medicinal and harming/detrimental senses. For example, Ayurveda recognizes a category of foods known as *tamasic*, the consumption of which is correlated with slowness, confusion, depression, and other negative qualities. This category includes processed foods, foods that are no longer fresh, as well as alcohol and synthetic intoxicants (Ragozina 2011).

At another level, a pluralist view also opens the possibility that there is not a singular, final way that we should conceptualize and practice medicine. This does not necessitate a default rejection of modern allopathic medicine, but an

interpretation of it as one of multiple perspectives on health and well-being that should be given legitimate consideration, alongside perspectives such as Ayurveda and Naturopathy that entail interpretations of the ontological categories of 'food' and 'drugs' as overlapping. The concept of "strength in diversity" resonates with this understanding. By creating access to an array of options that are taken seriously rather than dismissed, and by striving towards the ideal of having effective healthcare available to all, Indian medicine not only reflects the pluralism characteristic of Indian identity, but also creates the possibility for a more complete interpretation of health.

While the Ministry of AYUSH has made important strides in medical pluralism and access to healthcare, it has also led to difficulties and controversies that, I argue, are connected to its endorsement of interpretations that understand the food-drug relationship as overlapping. Some people have seen recent controversy as confirming that the promotion of traditional medicine is equivalent to "snake oil peddling" and quackery. For example, the Ministry of AYUSH released a pamphlet with advice for pregnant women in June 2017. Recommendations included the following:

Do not eat non-vegetarian food and please harbour spiritual thoughts. [...] Pregnant women should detach themselves from desire, anger, attachment, hatred, and lust. [...] Hang some good and beautiful pictures in your bedroom, which will have an effect on the (unborn) child also. [...] During pregnancy, women have to do self-study, should have spiritual thoughts, should read the life histories of great personalities and should keep themselves in peace (The News Minute 2017).

A number of commentators have critiqued these suggestions, pointing out the importance of non-vegetarian foods as sources of B-12, as well as data indicating lower maternal and infant mortality rates in Indian states with majority non-vegetarian populations as compared to states with higher percentages of vegetarians (*Ibid.*). Of course, while diets excluding meat can increase a person's risk for deficiency of certain nutrients such as iron and B-12, there is also ample evidence that a properly planned vegan diet, completely excluding animal products, can be healthy for humans at any stage of life, including pregnancy (Melina et al. 2016). Still, and especially from a more reductive medical perspective, a government agency's provision of advice regarding the hanging of pictures, detaching from desire, and making potentially drastic dietary changes (of any sort) during a particularly crucial and vulnerable period of one's life could reasonably be interpreted as lofty.

Besides calling attention to the quasi-mystical framing of these suggestions and their fuzzy relationship to scientific data, others have also critiqued the Ministry of AYUSH's pregnancy recommendations as co-opting and essentializing traditional medicine to re-instantiate and perpetuate patriarchal values. Subha Sri B., an obstetrician working with the Rural Women's Social Education Centre in Tamil Nadu, writes:

In the patriarchal discourse, the woman has been seen as merely an instrument to produce progeny and heirs to sustain the traditional family structure. These guidelines also essentialize the woman to merely be a vessel for a healthy child. For instance, the guideline says malnutrition in pregnancy can lead to anemia, rickets and bow knee *in the child* [emphasis mine]. While maternal nutrition is indeed an important determinant of health outcomes of the infant, it is ironic that the ministry seems to forget the woman at the centre of it all, and that malnutrition in the form of anemia is the biggest contributor to the large number of women themselves dying during pregnancy. The guidelines also equate pregnancy with motherhood, failing to acknowledge the needs of a whole group of women for whom pregnancy may not result in motherhood, when the pregnancy may not be wanted or may not result in a live baby (B. 2017).

This interpretation illustrates the extent to which institutional frameworks cannot be neutral, but are always already entangled and imbued with values and ontologies. This not only signals a concern that traditional medicine is being used by the Ministry of AYUSH as a patriarchal tool—a possibility that should clearly be taken seriously, especially in the larger context of spousal violence and emotional abuse in India and elsewhere (Tiwari et al. 2018)—but also raises the more general question of whether such entanglement is ever avoidable. Can pluralist perspectives on medicine and the food-drug relationship, or Ayurveda's recognition of the extreme uniqueness of efficacy and personal response to medical treatment, ever be adequately expressed within an institutional framework? This question shapes the trajectory of my exploration of the limits of an approach to regulating edible things that is premised on an interpretation of the ontological categories of food and drugs as overlapping with one another.

Lawyer and food law scholar Ajay Patel reflects on the ambiguities of food-drug regulation within a system that endorses the possibility of food as medicine, arguing that “the sale and promotion of foods in India based on traditional beliefs about their health and nutritional properties presents a tricky regulatory challenge” (2018). This challenge stems from the question of *how* governmental

authorities ought to evaluate edible things that are interpreted as both food and medicine. India has its own Food Safety and Standards Authority (FSSA) which is similar to the European Food Safety Authority in the European Union. However, Patel observes that many businesses in India that produce foods and market them as medicinal are not scrutinized by the FSSA in the way that other businesses are. Patel refers specifically to the Ayurvedic company Patanjali, which has claimed that its cooking oil “promotes hair growth” and that regular use of its honey “treats cough, cold and fever” and promotes “early healing of injuries” (*Ibid.*).

Patel argues that these and other products are not put through adequate scientific testing to support their associated medicinal claims, and he is not the only expert who has voiced this concern. In a 2017 interview, former Ministry of AYUSH Secretary Ajit M. Sharan stated that “the standards for licensing proprietary AYUSH drugs are pretty lax” (Bhuyan 2017). The lax standards are due to state-level authority over determining adequate testing, coupled with the somewhat vague national requirement that state licensing authorities “should be satisfied on the safety and efficacy of the new drug” (*Ibid.*) What counts as “safe” or “efficacious” in relation to specific medical claims is ultimately up to individual states to decide. In addition to the issue of authority and evidence, Sharan also describes the distinction between “classical medicines” and “proprietary drugs”:

There are two categories of drugs here. Classical medicines have been there for thousands of years. In terms of safety of medicines and efficacy, the fears here are largely unfounded. For others, there are good manufacturing practices which are mandatory. But how rigorously these are followed and how strong are our inspections and surveillance mechanisms, that’s an issue which is debatable. So in spite of these practices and certifications, the quality may still not be up to the mark. But if you stick to standard reputed brands, it *may* not be an issue [*italics mine*] (*Ibid.*).

While there are legitimate concerns here regarding control over traditional knowledge and the treatment of modern science as the final authority of what does or does not count as medicine, on the other side are also legitimate concerns regarding the potential abuse of vague standards for the sake of profit, as well as the acceptance of claims that are at best aspirational and uncertain, and at worst incorrect and manipulative. Patanjali has long argued that the edible things that it produces and markets as medicines should not be reviewed by the FSSA. This controversy recently resurfaced over the company’s well-known

amla (gooseberry) juice, which Patanjali argues is a proprietary Ayurvedic medicine with a license that has been cleared by the Ministry of AYUSH (Tandon 2017).

Secretary Sharan advises consumers to “look at the ingredients, the reputation of the manufacturer and take the indications with a pinch of salt, and you will be fine [sic]” (Bhuyan 2017). This is not bad advice for any product purchase, but in the current context the *caveat emptor* perspective should also be taken with a grain of salt, as it is emerging from within a system that could reasonably be criticized for placing undue pressure and responsibility on citizenry who are trying to preserve their well-being *and* who would like to trust that products available to them are in keeping with the traditional knowledge that India has fought so hard to bring into the mainstream. While the Indian government has taken important steps in preserving and promoting its traditional knowledge on health, food, and medicine, their regulatory structure’s endorsement of interpretations of the food-drug relationship that understand these categories as overlapping has also opened the possibility for the exploitation of its ambiguities.

6. Evaluating Dichotomous Interpretations in Regulatory Policy

A general assessment of clusters of interpretive lenses will always be limited and incomplete, but is also useful in appreciating the difficulties and dangers in treating any variety of framing as monolithic. Thus, in this section I provide some brief evaluative remarks on dichotomous food-drug interpretations.

One virtue of dichotomous food-drug interpretations is their comparative simplicity. Philosophers and others have long recognized and valued simplicity in explanations, as evidenced by argumentative heuristics such as Occam’s Razor. If there is a hard ontological distinction between the categories of food and drugs, this makes it relatively easy to tell food and drugs apart from one another. This can be beneficial for legal purposes, as the production, regulation, and distribution of substances depends to some degree on whether they are classified as a food or drug.

This view also lends itself to a straightforward method regarding the ways that substances should and should not be used in the treatment, curing, and prevention of health problems. This does not mean that, on this view, one’s diet has no bearing whatsoever on health. For example, a dichotomous interpretation of the food-drug relationship can still take into account the empirical research on the role that a healthy diet can play in preventing chronic

diseases such as coronary artery disease, stroke, and some cancers (Willett et al. 2006). Further, regarding chronic inflammatory illnesses such as Crohn’s disease, a dichotomous interpretive schema can also be compatible with recognizing that some patients can identify (and avoid) foods that trigger inflammatory responses, while simultaneously recognizing that “there is no special diet that is recommended for treating inflammatory bowel disease (IBD)” (Cunha 2020).

It is possible to recognize that an array of factors influence one’s health without also seeing this influence as grounds for understanding those factors as drugs. However, a dichotomous approach to interpreting the food-drug relationship supports the view that doctors ought not *prescribe* those substances that provide sustenance for medical use, though they may be seen as helpful or harmful to some extent. Drugs are prescribed by physicians on this view, while food is not. Further, this entails that physicians are distinct from dietitians and nutritionists, though their services may be used in conjunction for greater overall health. While food is seen as distinct from drugs, this obviously also necessitates that drugs are seen as distinct from food. Drugs are typically taken to lack nutritional properties and are not considered to be sustenance.¹

Another virtue of dichotomous interpretations of the food-drug relationship lies in their increased vigilance regarding fraud. A multitude of people have insincerely presented substances including edible beings/things (e.g. snake oil) as straddling the fence between these categories as special healing elixirs, with little or no basis for their claims aside from a profit motive. Interpreting food as something that cannot also be a drug is one potential (though not necessary) outcome of a broader reductive scientific framework that entails a view of drugs/medicines as synthetic products of technology that have refined, improved, and sometimes drastically altered “natural” substances. Those edible things which people interpret (or deceptively present) as drugs or medicines, but which do not meet the standards of scientific evidence (or which have not yet been subjected to these standards), are simply foods. *Or*, if they end up meeting

¹ The recent emergence of nutrition education and the food pharmacy model within U.S. medical practice marks a distinct interpretive shift, introducing elements of interpretations of the categories of ‘food’ and ‘drugs’ as overlapping into a largely dichotomous ontological schema. Within certain contexts and locations, some doctors and other members of the mainstream medical community have embraced an interpretation of food and drugs as overlapping, rather than existing as fundamentally distinct sorts of entities. See Ren (2017) for further discussion of food pharmacies in U.S. contexts.

the standards for something to be a drug, *then* they are drugs, and need to be regulated and distributed as such. This entails a judgment that the substance in question not only treats or cures conditions as advertised, but that it is also safe enough to be prescribed or sold over the counter to the public.

In tandem with the virtue of discerning quackery, nutritionism and related scientific ideologies have the added advantage of providing a rigorous, systematic basis for testing health-related claims about edible things. Science is still interpretive, value-laden, provisional, and fallible, but these are essential components of any human endeavor. At the end of the day, it still gives us something more to go on than loosely regulated marketing claims or the words of others in the absence of sufficient evidence.

When drawing a hard line between the categories of food and drug, one potential vice stems from potential classificatory difficulties when parties are “forced” to categorize edible things as members of one or the other ontological set. That is, on the assumption that these categories are ontologically distinct from one another, one could still end up being “wrong” about the category in which a given substance should properly be included as a member.

Another potential vice of dichotomous interpretations lies in the cultivation of a skeptical sensibility that is overreaching. It engenders a dogmatic commitment to a dichotomous interpretation of the food-drug relationship that can be unwavering. Those with more calcified views who have embraced a dichotomous interpretation may then approach differing interpretations as inherently inferior to their own. On such a view, a purportedly boundary-breaking substance or practice is “snake oil” until proven otherwise. In this way, rejecting the blurring of food and drugs is often, though not necessarily, linked to the disparaging of other interpretive modes.

While caution is plausibly warranted, and even virtuous, in our interpretations (in addition to the observation that we cannot just automatically shift our interpretations with the flip of a switch), an overly-cautious approach risks hastily closing off potentially fruitful and transformative ways of understanding and experiencing oneself in the world, as well as hastily judging the views of others without being sufficiently critical of one’s own approach. Of course, the risk of zealotry is not unique to dichotomous interpretations of the food-drug relationship, but it is important to consider the unique ways that it may manifest in the context of regulatory policy.

7. Evaluating 'Overlapping' Interpretations

Though the situated nature of experience should encourage an openness to myriad interpretive modes, it also does not hurt to consider possible interpretive implications in advance of future experiences. For example, food psychologist Kima Cargill adeptly characterizes competing interpretive modes in the sugar regulation debate:

Because sugar is one of the few substances increasingly thought of as both a food and a drug, I argue here that it has become a flashpoint for two kinds of fear pandemics that have historically followed each—drug moral panics and nutritional scapegoatism. Sugar has taken on a symbolic valence in the current zeitgeist, mediating a see-saw of opposing forces governing the collective unconscious. On the one side is regression, pleasure, and intoxication—all historically viewed with moral suspicion and subject to suppression, control, and regulation. On the other side is scientific consensus, public health, and consumer protection. Underpinning (and perhaps fomenting) this tension is the impossibility of defining what makes something a drug (Cargill 2016).

“Without this kind of hermeneutic lens,” Cargill argues, “the reporting of scientific research in both academic journals and mainstream media takes on the appearance of unassailable, objective truth” (*Ibid.*). Once we reject the preoccupation with discovering “unassailable, objective truth” regarding food-drug interpretations, we can then begin to consider the various dimensions of different *sorts* of interpretation. People on both sides of the sugar regulation debate are often trying to push and co-opt narratives for questionable purposes, and this is reason enough not to simply accept a particular interpretation as the given truth. Instead, we must do our best to consider the benefits and the blind spots of differing lenses.

Instead of feeling the illusory need to figure out or to choose whether a given substance is either a food or a drug, a virtue of overlapping interpretations is that they allow us to recognize that many substances display qualities of both food and drugs, and that interpreting a substance as a member of one category need not preclude it from being interpreted as a member of the other. For example, we can acknowledge the potentially addictive nature of sugar without simultaneously having to make the claim that sugar is not really a food because of its potential toxicity and addictiveness. Clearly, not all food is inherently “healthy,” and the very concept of health itself is ever-elusive and difficult to pin down (Gadamer 1996).

Interpretations of the categories of food and drugs as overlapping not only come with the virtue of interpreting substances as having both food and drug-like properties in the negative sense, but in the positive as well. For instance, ginger root has long been recognized within the Ayurvedic tradition as possessing myriad medicinal properties, and this has not disqualified it from also being interpreted as a food. In fact, it is utilized extensively throughout different Indian culinary traditions due to its purported stomach-settling and anti-inflammatory properties as well as its spicy flavor. However, because of the tendency to dichotomize food and drugs, much skepticism is encountered in the recognition of food as medicine. This is at least partially due to a particular hermeneutic which can be examined to consider possible deficiencies with dichotomous interpretations of the food-drug relationship.

A vice of an overlapping approach to the food-drug relationship, in contrast to a dichotomous approach, is the lack of simplicity in the classification of substances. In the legal sphere, for example, it is generally assumed that certain lines need to be drawn, even if it is acknowledged that these lines are somewhat arbitrary. If we adopt an approach to the classification of food and drugs that interprets these categories as overlapping, this may complicate attempts to delineate boundaries for regulatory purposes. In the current system, drugs are obviously regulated much differently and more heavily than food. However, if one adopts the view that at least some substances can legitimately fall into both categories to different degrees, then more thought will need to be put in to the legal treatment of particular substances.

A further vice of an overlapping approach is the historical difficulty of separating quackery from legitimate medical theory and practice, and the general skepticism that this difficulty has engendered. There is serious cause for concern regarding medical fraud that also bleeds into skepticism regarding the possibility that an edible thing does not fit neatly into a food/drug dichotomy. Even considering the people who truly believe in the medicinal properties of certain substances commonly thought of as food, or the nutritional potential of substances commonly thought of as drugs, our beliefs can be, and often are, mistaken. This is not merely a limitation of the human mind, but it can also have palpable negative impacts as evidenced in cases of trickery for the sake of profit, as well as bodily damage to those who mistakenly trust an alleged source of authority and knowledge. Our interpretations of the ontological statuses of edible things are inextricably bound up with epistemological and ethical concerns: Is something a food, a drug, or a bit of both? How can we know this well enough to make reliable

judgments? How ought we to treat these substances in accordance with an interpretive schema?

The importance of degrees must also be considered on overlapping interpretations. A given substance may have a few properties that are seen as drug-like, while having an overwhelming number of properties that are food-like, and vice versa. Various pills and synthesized medicines, for instance, may have little or no nutritional properties, essentially providing no sustenance for the user. So, the possibility must also be left open for certain substances to simply be interpreted as drugs rather than food (and vice versa). However, an overlapping approach can allow for this, since it does not imply that all substances are equally food and drug-like, but simply allows for overlap within a larger ontological spectrum.

8. Giving Difference Its Due: Dialogue on the Food-Drug Relationship

The dialogical structure of philosophical hermeneutics provides a useful foundation for unearthing and examining the ontological commitments undergirding food and drug regulatory policy. As illustrated in the concept of the hermeneutic circle, understanding is itself a process of continual refinement through dialogue between parts and wholes. My interpretation of a particular edible thing as a food and/or drug is informed by my various presuppositions: my past experiences with those (or similar) edible things, my implicit endorsement of some interpretation of the relationship between the ontological categories of food and drugs, my consideration of other viewpoints through literature and conversation, and many other possible factors that shape my prejudice when entering into a given experience. In turn, those particular instances also shape my understanding of the related ontological categories.

This dialogue extends beyond our own individual experiences and intertwines with dialogue between persons and groups. Charting a course between objectivism and relativism, we are left to compare our “field notes” with one another in the service of mutual development and understanding. Engaging in genuine, good faith dialogue requires us to reflect on the conditions for actualizing this possibility. On this topic, Gadamer argues:

[...] In a successful conversation [both partners] come under the influence of the truth of the object and are thus bound to one another in a new community. To reach an understanding in a dialogue is not merely a matter of putting oneself forward and successfully asserting one's own point of view, but being transformed into a communion in which we do not remain what we were (Gadamer 2012[1960], p. 371).

A successful conversation is not about taking a combative stance in an attempt to “win” over your opponent and to demonstrate that they are wrong. Reaching an understanding does not require forming a compromise or ending in a situation where both sides share a perspective. Instead, it calls for openness in both conversation partners to really hear one another out, to avoid dogmatism (both in favor of their own view and against the other’s), and to alter or retain their position in light of dialogue and critical reflection.

Paul Healy elaborates on this point in his defense of a “hermeneutico-dialogical” approach to intercultural communication and understanding (2013, p. 266). Healy’s approach consists of the application of two principles: comparable validity and dialogical equality. Comparable validity requires us to go beyond merely positing intelligibility or assuming cross-cultural similarity in a way that minimizes or distorts difference. Instead, it calls on each culture involved in the dialogue to “allow the other culture to challenge our existing presuppositions, recognizing that it is likely to embody ways of viewing the world and of thinking and reasoning about it previously unfamiliar to us but from which we could profitably stand to learn” (*Ibid.*, p. 273). This principle entails positing a culture’s holistic integrity and richness of meaning as a default perspective when entering into dialogue, rather than assuming the opposite until given reason to believe otherwise.

Alongside this recognition, dialogical equality calls on conversation partners to avoid presupposing that they are better able to represent one another’s perspectives. Instead, Healy argues that one culture should allow the other to “articulate its self-understanding in its own terms and, attending carefully to fundamental differences in ontological, epistemological, and valuational presuppositions, stand ready to modify our existing preconceptions in the light of what we thus come to learn” (*Ibid.*). This point brings us back to Gadamer’s reflection on dialogue and the transformation of conversation partners into a communion in which “we do not remain what we were” (Gadamer 2012[1960], p. 371). Rather than hone our skills of sophistry for the sake of besting and gaining power over the other side of a debate, dialogue requires us to forego this in order to work towards mutual understanding among interpretive modes.

While it seems crucial to cultivate this sense of openness to other perspectives and the self-critique of our own perspectives, it is also true that we can never *actually* see things from the perspectives of others. Remarking on this in the context of scientific paradigms, Kuhn writes that “the proponents of competing paradigms practice their trades in different worlds” (1996[1962], p.

150). The diversity and multiplicity of presuppositions that each of us brings to our experience and understanding cannot be exhaustively articulated let alone replicated in the experience and understanding of someone else. There are sometimes grounds for degrees of overlap, and sometimes not, but we are not able to see through the eyes of another. At the same time, it is important to make efforts to *imagine* what it might be like, and to posit that there *is* something that it is like, rather than casting doubt on the other's subjectivity and interpretive legitimacy.

Applying this hermeneutico-dialogical approach to the food-drug relationship, the first step is for conversation partners to acknowledge that their understanding of this relationship is interpretive. They do not have unmediated access to a mind-independent reality, and the terms 'food' and 'drugs' do not necessarily refer to natural kinds. In recognizing the implications of understanding experience as mediated, my work here is also supported by David Ludwig's recent arguments regarding the importance of moving away from talk of "natural kinds," as this concept raises legitimate concerns about the risk of essentializing biological categories as well as its leading to a failure to take seriously Indigenous and other classificatory frameworks on their own terms (2016). As Ludwig and Weiskopf observe, "Indigenous and other local ontologies are not just philosophically intriguing but also a crucial component of practices and traditions that support the livelihoods of local communities" (2019, p. 8). Taking this into account provides a strong basis for suspending the imposition of dominant ontological schema in an effort to avoid subordinating, delegitimizing, and oversimplifying the multiplicity of ways in which people understand themselves and their worlds.

There is no reason to assume that there is one single, correct way to interpret particular edible things, and all interpretations likely have different degrees of strengths and blind spots. Food-drug interpretations are bound up with larger worldviews, holistic systems that generate meaning for their adherents. Granting this, conversation partners can seek to gain a clearer picture of differing interpretations, what they can learn from these interpretations, and how they can interrogate their own interpretive modes. For example, an Ayurvedic practitioner can appeal to traditional knowledge in favor of an 'overlapping' perspective of the food-drug relationship while also cultivating a critical stance regarding the identification and testing of potentially fraudulent herbal medicines. Allopathic physicians can research the cultural and historical contexts that have influenced Ayurvedic and other traditional systems of health,

including the use of edible things that they might interpret as “food” for medicinal purposes. Psychologists can point to possible neurological discrepancies between drug addiction and habitual overconsumption of food, while also seeing potential practical significance in a clinical interpretation of foods that could also reasonably be interpreted as addictive drugs. Most importantly, conversation partners can create spaces where they are genuinely sitting down to talk with one another, making space for explicit philosophical and practical dialogue, rather than critiquing caricatures of one another.

Of course, this kind of dialogue has already started to happen in certain contexts. One recent noteworthy example is the first India-U.S. Workshop on Traditional Medicine in New Delhi during March 2016. The workshop was a collaboration between India’s Ministry of AYUSH, the U.S. National Cancer Institute (NCI), National Institutes of Health, the Office of Global Affairs, and the U.S. Department of Health and Human Services. According to the speakers at the workshop’s welcome address, its goals were:

[T]o discuss the importance of applying rigorous scientific methodologies to the study of traditional Indian medical systems, using evidence derived from such studies to inform both traditional medical practices, appropriately integrating evidence-based traditional practices with modern (Western) medical practices, and making use of the particular strengths that India and the United States can bring to this endeavor (White et al. 2017, p. 3).

While coming to an understanding through dialogue doesn’t require a purposeful fusion of two differing interpretations, it is interesting to see the ensuing conversation as represented in an overview of the workshop sessions. In one session, for instance, a scientist from the Indian Institute of Chemical Biology discussed the anticancer properties of a molecule derived from curry leaves (*Ibid.*). In another, scientists from Yale shared their research on similar anticancer effects of administering a traditional Chinese medicine formula, currently being used in clinical trials with advanced colorectal cancer patients (*Ibid.*). Workshop attendees worked in groups at the end of the workshop to generate recommendations for future collaborative work. Attendees pointed out a critical need to ensure product integrity and safety of AYUSH products, but also included a call to focus on the strengths of traditional medical systems, and even the need to “harmonize pharmacopeias between India and Western nations” (*Ibid.*, p. 6). This workshop is just one example of communities with disparate interpretive modes uniting with a genuine interest in openness and learning

from one another, as well as continuing to collaborate on future projects to benefit the larger world.

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