Normal, Regular, Standard: Colonizing the Body through Fecal Microbial Transplants

Abstract: In 2013, the National Institutes of Health and the Food and Drug Administration held a workshop to determine the risks and benefits associated with the experimental use of fecal microbial transplants to treat Clostridium difficile and other gastroenterological disorders. By focusing on the proceedings of the NIH-FDA workshop on the treatment of the human microbiome, the question of how medicine colonizes human bodies through microbial transplants raises questions about what an individual body is, how determinative of human health the microbiome is, and what the limits of molecular biomedicine are when the microbiome is taken into consideration. In the workshop presentations and discussion of this emerging treatment, experts use ideas about the normal, regular, and standard to move between scales of bodily analysis, from the microbial to the body politic, demonstrating how the individual and society are deeply influenced by the unruly community of microbial symbiotes humans host.

Keywords: Governance, Biopolitics, Capitalism, Regulation, Microbiology

Clostridium difficile (C. diff) is a naturally occurring microbe in the human gut, one of many hundreds of identified microbes that comprise the human microbiome. In a healthy body, C. diff. is unproblematic – it is one of many microbes that is relatively benign as part of the whole community. But when an individual takes a broad spectrum antibiotic medication, the microbial environment of the gut can change so as to wipe out many of the microbes that hold C. diff. in check; with their competition gone, C. diff. blooms to the point of colonizing the gut. This leads to dysentery, and many individuals with C. diff. report having to go to the bathroom hourly in addition to needing to wear diapers to protect their clothing and furniture, a profound social disruption akin to other disorders to the gut, bowels, and bladder (Lea 1999; Manderson 2011; Mitteness and Barker 1995; Ramirez, et al. 2014). As one might expect, it also leads to dehydration and malnourishment, and for many individuals who took antibiotics for a primary concern other than C. diff., this can be a life-threatening situation. The most thorough accounting of this patient population claims that about half a million Americans will have a C. diff.

infection each year, and that about 15,000 of those will have recurrent C. diff., meaning that it fails to respond to first line treatment, which is to use another antibiotic (Lessa, et al. 2012; Surawicz, et al. 2013). These 15,000 patients are those seeking fecal microbial transplants (FMT), a treatment which proves to be about 90% effective (Rohlke and Stollman 2012). FMTs can occur through two routes, the top or bottom. In the case of a top procedure, a gavage tube is inserted nasally, and the transplant material is pumped past the stomach and into the intestine; in the case of a bottom procedure, an enema solution is prepared and inserted into the colon. In both cases, the patient is charged with holding the solution in their body for as long as possible, which can last minutes or hours depending on the constitution of the patient. The solution is based on donor feces, often provided by a friend or family member of the patient, which has been tested for possible infectious microbes, blended with water and strained. The clinically preferred method of delivery is through the top, as it is generally assumed to be more effective (Brandt 2012; Zipursky, et al. 2014), but enema as the technique is easier and less objectionable to most patients, and is more popular, particularly in cases of self-administration. The administration of the solution occurs daily, often for weeks at a time, although significant changes are reported by patients as soon as within 24 hours of treatment.

Given that the donations come from friends and family members and that the method of delivery is relatively easy, many individuals attempt self-administration. This is aided by websites like Power of Poop and a Facebook self-help group, as well as many other websites and scientific papers that provide guidelines for testing donor feces and self-administration. Moreover, FMTs are not covered by many – if any – medical insurance plans in the U.S., and physicians complain of lack of reimbursement for the

procedure: they can fiddle with reimbursement codes, but cannot charge for the procedure as such, which has led to reports of many patients paying as much as $10,000 for the procedure out of pocket. Since many patients are significantly beset by the C. diff. infection, they are willing to pay; or, if they are able and willing, treat themselves at home. During a period in which the Food and Drug Administration (FDA) imposed an Investigative New Drug (IND) protocol restricting the use of FMTs to approved clinics, many patients conducted their own treatment, with or without clinical oversight, potentially leading to more risky procedures, harm to already sick individuals, and endangerment of the procedure's reputation and scientific validity.

In this article, I am focusing on a workshop held by the National Institutes of Health (NIH) and FDA in May of 2013 on the subject of FMT, their risks and clinical applicability.[1] By focusing on the ways that participants spoke about the microbiome, individual bodies, and forms of treatment, we can see how discursive registers are employed to produce bodily scales, from the smallest microbe to the body politic. Typically, when social scientists discuss scale, they are considering the move between the local and global, particularly in relation to the economic (e.g. Tsing 2000); herein, I focus on how scale operates to conceptualize bodies, medical action, and the 'colonial' project of FMT as a means to consider how scale operates in the context of medical governance. In so doing, the risks associated with the human microbial colony become apparent, as do the problems with attempting to regulate these microbial colonies – and the people whom they inhabit. By focusing on this metaphorical 'colony' and the registers through which medical professionals conceptualize bodies, disorders, and treatments – the 'normal,' the 'regular,' and the 'standard' – some of the limits of contemporary medical governance

can be elucidated, namely that individuals are much easier to control than microbial colonies are. In a context where microbial colonies are determinative of human health, but in which there is no definitive ability to control the colony or its effects, medical governance becomes thwarted and in need of reconceptualizing what a body is and how it is shaped.

What's at Stake in the FMT Debate?

The NIH-FDA workshop featured talks by scientists, clinicians, an entrepreneur, and regulatory officials from the FDA, all focused on the perceived risks and benefits of FMT. The NIH and FDA initiated the meetings due to a surge in popularity of FMT since 2011, used primarily as a treatment for C. diff. infections, due to the low risk and high success rate of FMT. At the time of the workshop, the FDA had recently imposed the need for clinicians to file an IND application for the use of FMT, effectively curtailing the ability of clinicians to use the treatment outside of large research hospitals with the staffing to prepare the hundreds-of-page-long IND application. Of the many attendees, only one was a prior recipient of FMT, Catherine Duff, and her testimony came at the end of the two-day workshop in an open question and answer period, not as a formal presentation:

> I'm one of those people who call and email you everyday. I've had eight episodes of recurrent C. dif and it's now antibiotic-resistant. I cannot find a doctor who will perform an FMT so my husband and I did it at home ourselves. Within 24 hours my symptoms were gone and I remained symptom and toxin-free until the next time I had to take antibiotics.
>
> At that time, one of my team of physicians agreed to perform an FMT without knowing what an IND was, that one was required, or that a CPT code had been assigned. He did perform it in his surgical outpatient clinic and again within 24 hours, I had no symptoms. I remain symptom-free and toxin-free

> as of October of last year.
>
> People are desperate for this treatment. As doctors, clinicians, researchers, administrators, you know the stories of your patients, but you have not lived our lives. You have not felt our dwindling hope and our growing sense of despair. I now wonder each and every day if I will be able to have another one if needed, what I will do if it ceases to work, and what will I do if I encounter a different superbug.
>
> Currently physicians use many, many biologics. The risks are explained to and generally accepted by the patient. Speaking for the hundreds of thousands of people that cannot be here today, please go forward, be bold, be courageous, find a way to quickly, without several years of preclinical and clinical trials, allow qualified doctors to perform FMT with tested donors and signed consents without fear of regulatory consequences.
>
> If your spouse, child, parent, sibling, or best friend were dying from antibiotic resistant C. dif, I imagine that all of you would want them to be able to try FMT and I imagine that most of you would agree to be the donor and to even perform the procedure yourself if necessary. People are dying everyday, today, right now.
>
> I have a wonderful husband, three amazing daughters, and two small grandchildren, and I want to live. All of us just want a chance to live. Please, do something not only for me, but for all those around the country and everywhere who have no insurance, no financial resources, no computer with which to Google information, and no hope. Please do something quickly.

Duff lays out what is at stake in the workshop and the FDA's disallowance of clinicians to use FMT as a treatment: the FDA is afraid of the consequences of the treatment for individual patients and their physicians, who may face legal malpractice suits. Yet physicians are willing to perform FMTs because they recognize it as relatively safe and effective – and patients are willing to adopt the risks associated with FMTs because they are facing a humiliating, debilitating, and potentially life-threatening disorder. With the new IND paperwork requirements in place, the FDA had effectively shut down access to FMTs for patients living anywhere but near major research hospitals. This resulted in many patients self-administering FMTs with the help of friends and relatives – a much riskier situation than seeking a medical professional. Along with Duff's moving testimony, these factors might be enough to dismantle the IND restrictions, but in this

article I point to some of the scientific testimony that even further troubles the ability of the FDA and physicians to regulate individual behavior and treatment outcomes, all of which circulates around the constitution of the microbiome as a 'matter of concern' (Latour 2004) and its effects on American everyday life. Humans may be easy to govern, but the microbiome is much more unruly.

Given Duff's testimony, the results discussed by the clinicians and scientists at the workshop, and the risk of self-administered FMTs, the FDA eventually decided to "exercise enforcement discretion,"[2] effectively allowing clinicians to perform FMTs with only the informed consent of the patient, thereby circumventing the IND restrictions. Despite intense regulation and fear associated with medical malpractice and the discrediting of the science used to support FMTs as a procedure, the FDA decided to allow FMTs to proceed unimpeded by governmental regulation because of two factors: first, it has become challenging to govern patients and their access to medical techniques and knowledge, as made evident in Duff's and others self-administration of FMT; and, secondly, the human microbiome, which FMT relies upon, fundamentally troubles medical governance in its unruliness. The modern state, which has never had a firm hold on the governance of medicine and its practice (Porter 1999), is increasingly losing its hold due to the decentralization of medical practice and the dawning reality of the body's irreducibility; the microbial communities that make up a human's microbiome defy any easy attempt at control, either environmentally or chemically. The testimony of the clinicians and scientists at the NIH workshop point to this reality, although indirectly; throughout the proceedings, presenters offer images of microbial communities as unpredictable, unknowable, and difficult to manage for individual patients and medical

staff. Rather than the transparent biopolitics that can be seen in much of modern American medicine – from the racialization, gendering, and classing of bodies through pharmaceutical markets (Dumit 2012; Kahn 2012; Metzl 2003; Rouse 2009), to genomic screening (Rapp 1999; Taussig, et al. 2003), to differential cancer exposures (Jain 2013; Stacey 1997), to HIV/AIDS interventions (Epstein 1996; Marshall 2005) – FMT and the human microbiome exposes how biopolitical governance fails to capture all communities – human and not – that make up the modern populations that comprise the body politic. We have entered an era of what Heather Paxson names 'microbiopolitics' (2008), but without the apparatuses to predictably govern the forms of life that make up the microbial world we are a part of, either chemically or politically.

In the following three sections, I focus on the ways that medical professionals talk about and conceptualize the body and its relation to FMT: first, how the metaphor of 'colonization' is used to construct the patient's body as a passive medium to receive an FMT treatment (Lakoff and Johnson 2003 [1980]; Martin 1991; Martin 1994), the goal of which is to render the patient 'normal' as an individual body. Second, I consider how the abnormal is regularized through a consideration of what 'normal' looks like when brought to bear on the human digestive system. The human gut depends upon 'regularity' in a temporal frame, at the level of the microbial, physiological, clinical, and institutional. Finally, I follow the movement from regular to standard, which in this case is principally informed by concerns about the market. In this case, standardized products are sought to make human bodies 'regular,' working from the body's microbial constituents up to the individual body. From the normal, to the regular, to the standard, patients, physicians, and researchers are scaling down, conceptualizing smaller levels of scale, their

determinative effects on health, and how they might be acted upon; they also scale up, focusing on the health of microbial communities to explain the health of individuals – and sometimes whole societies. 'Normal,' 'regular' and 'standard' are generally taken to be synonyms, but, as demonstrated by the proceedings, each has a valence shaped by ideas about the level of analysis that is being discussed by physicians and researchers. In tracking the shifts between these frames, the scale that is used to think about the body and its iterations can be apprehended, as can the conceptual mechanisms through which shifts in scale are made. In making these shifts, the body is constructed through medicine and science as existing in tension between a medically-governed body politic as one of many biopolitically produced similar bodies, and the microbial body, comprised of a population of unruly and unknown potentials that defy medical, scientific, and lay conceptions of discrete human bodies.

From the Molecular to the Microbial and Molar: Bodily Scales of Colonial and Governmental Action

The individual human body is popularly understood as a discrete object, contained within its skin (Armstrong 2002), with its health determined primarily by internal, causal mechanisms, although these may be exacerbated by environmental or lifestyle influences. In order to capture the complexity at work in recent biomedical and scientific paradigms, it is necessary to add two subdermal ways for thinking about the body, namely the molecular and the microbial, the first of which is evident in interest in genomics and pharmaceuticals, whereas the latter is most clearly demonstrated in medical and scientific attention to the human microbiome.[3] In adding these layers to the body, it becomes

apparent how colonization operates at the level of the individual, what its mechanisms are, and how it succeeds and fails. 'Colonization,' here, is an emic term, used by microbiologists, gastroenterologists, patients, and clinicians to describe the process of introducing a 'good' microbial community into an unhealthy gut. In the case of the molecular, science and technology studies and medical anthropology have focused attention on genomics and the use of genetics in biomedicine since the initiation of the Human Genome Project in the early 1990s, often laying emphasis on how genomic knowledge production and practice depends up and reinforces entrenched ideas about race, ethnicity, age and gender (Montoya 2011; Pálsson and Rabinow 1999; Rabinow 1996; Rapp 1999; Reardon 2004; Taussig 2009; Whitmarsh 2008). The molecular body is ruled by discourses about the genetic and epigenetic and moves analysis beyond the 'molar body'[4] to its chemical underpinnings; equally important here are chemicals, from pharmaceuticals to hormones, that are seen as affecting the behaviors and capacities of individual bodies (Dumit 2012; Oudshoorn 1994; Oudshoorn 2003). As such, the molecular body is often perceived as being highly deterministic in its effects, and serves as a register for conceptualizing the limits of agentive human powers. That is, the molecular is often perceived as being determinative of our human capacities, particularly at the individual level, where genes or brain chemistry are popularly accepted as shaping the agentive powers of particular people in specific ways – for example, the depressed brain (Martin 2007), the psychotic brain (Dumit 2003), or the congenitally disabled (Heath, et al. 2005; Rapp, et al. 2001).

Beyond the molecular body is the microbial body, the many nonhuman actors that live upon, in, and with human populations. The microbial body is the body as multitude,

the individual body as body politic (Scheper-Hughes and Lock 1987), comprised of a variety of communities of different species that may shape the individual and his or her capacities for digestion, stimulus response, and, potentially, psychological well being (Sun and Chang 2014). Microbial colonies, good and bad, are unruly and difficult to predict, manage, and effectively treat. Microbial communities are affected by the molecular, and treatments like antibiotics are specifically designed to act upon the microbial body, sometimes beneficially by eradicating a bacterial infection, and at other times leading to an imbalance in the microbial body which results in C. diff or similar problems of an unruly colony. The molecular and microbial have synergistic capacities for changing the individual body, both through molecular therapies, and, as in the case of FMT, through microbial ones as well. Microbial colonies open the question of whether biomedicine's ability to govern the body politic is being significantly challenged in the context of a society that increasingly focuses on the dietary and health benefits of a diverse microbial environment (Chutkan 2015). The molecular and the microbial add smaller scales to conceptualize the body, moving downward in size beyond the encapsulating flesh of the individual body to imperceptible actors inside the body. In scaling down in these ways, the individual becomes less a discrete, skin-contained object, and more a world comprised of microbial populations and molecular forces.

As it becomes difficult for medical professionals – and the U.S. government itself – to control the behaviors of individuals, particularly in the case of self-administering FMTs, as discussed throughout the FDA proceedings, recourse is made by clinicians, scientists, and bureaucrats involved in the NIH-FDA workshop towards 'standardization' provided by capitalist investment in manufacturing therapies that will produce governable

subjects through medical intervention. This can be seen in the workshop by the interest in producing FMT kits that will produce 'normal' microbial colonies in their recipients, and thereby render the individual body normal as well. As scholars of American medicine have shown, there is a strong trend in medicine towards the normalization of individual patients (Davis 1995; Dumit 2012; Porter 1999 [1997]). This can be seen in pharmaceuticals that shape affect, particularly antidepressants (Healy 2006; Martin 2007), but also treatments that shape everyday behaviors, like sleep (Wolf-Meyer 2012), menstruation, and reproduction (Martin 1992 [1987]). As Elizabeth Dunn has pointed out in the case of post-socialist Poland, 'standardization' plays a vital role in the capitalization of consumer goods that are intended to maintain health and the normal functioning of the individual – in her case, that of babies through baby food (2004). Similarly, presenters at the FMT workshop used 'standardization' particularly in relation to the development of particular kinds of FMT kits to be bought by patient-consumers; they also used it to think through the contents of any particular microbial community and whether or not it was reflective of a 'normal' human microbiome. In both cases, what was central to their conception of the microbiome was the individual human body of the patient and how a patient might be turned into a healthy individual through 'colonization' with FMT. By conceptualizing the microbial as determinative of an individual's health, the participants in the NIH-FDA workshop were trafficking between the scale of the individual body and its microbial constituents. The right, possibly standardized, microbial community would produce a normal individual.

FMT and gastroenterology offer a model of medicine as a colonial practice, as they often rely upon metaphors about 'community' and 'colonization' to conceptualize

the target and effects of microbial-based disease and their potential therapies. This language is at once metaphorical and based in the reality of medical practice: microbes are colonizing bodies with the goal of displacing the existing microbial community and replacing it with a new one. As a site of colonization – and comprised of a native population, albeit of microbes – the human body is subject to medical governance, as is its microbiome.[5] Humans, as long as they are compliant with the expectations of medical professionals and insurers, tend to be easily governed. But microbial communities prove much more difficult, as they are difficult to document – there is no microbial census – and also unpredictable in their reactions to treatment. In focusing on these communities, questions are raised about medical governance as it is applied to the molecular and microbial bodies. By focusing on the microbial and molecular, the difficulties of modern medical governance can be elucidated, exposing how the control of life at multiple scales – from the molecular to the microbial to the molar – becomes desirable and ultimately unattainable.

From Abnormal to Regular: Stabilizing the Microbial Body in Temporal Patterning

In the following section, I draw on speakers at the NIH-FDA workshop who each use the normal as a way to conceptualize the microbial colony inhabiting a human body, and how these colonies determine the normalcy – or lack thereof – of the individual body. With this basis of the normal, speakers then discuss the need to 'regulate' the microbial colony, individual body, and institutional demands as a way to temporally situate the normal; through 'regulation,' the normal unifies bodies across scales, from the microbial to the individual to the institutional.

During the FDA proceedings, Lita Proctor, the Director of the Human Microbiome Project, provided an example of how the normal comes to be used to conceptualize the microbial body, its internal changes, and their influences on the individual body. Foundational here is how the normal and the healthy become rendered as isomorphic, and how "healthy" becomes a mechanism to reduce the individual to the microbial.

> …it's very hard to define healthy. So, as the way that the [Human Microbial Project] defined healthy was to actually consult a wide variety of specialists in each part of the body and talk to them about what would they consider a healthy or a normal condition of that body site. And so, a combination of inclusion and exclusion criteria were utilized to define healthy in this kind of super-healthy or carefully vetted cohort. (May 2, 17)

During the question and answer session following her presentation Proctor went on to explain, "I would have to say [the participants] were young and they were super healthy. So, yes, that's not necessarily the same thing as normal. Right? Right." (May 2, 33). "Healthy" is taken as equal to "normal" when referring to the individual and his or her microbial body; "super healthy," which she uses to refer to the participants in the HGP who had been carefully screened for microbe-impacting conditions or behaviors, is expressly set against the normal: the "super healthy" are not normal but help to show what the expectations for medical research are, and who counts when it comes to developing knowledge about the human body.

Among the many presenters were a small number of animal microbiologists and veterinarians. Among veterinarians, FMT has a longstanding role in everyday practice, where is it referred to as "transfaunation" (DePeters and George 2014). Veterinary science – to the extent that large mammals provide models of human biology – provides a parallel set of evidence that is coming to be interpreted as relevant for thinking about

FMT among human populations. Linda Mansfield, a microbiologist from Michigan State University, provides a view of how many large animals are affected by transfaunation, leading to what she refers to as "a new normal" after illness and a period of treatment:

> …if we look at the relationships between these microbial communities from different times we see that in pet one, on day one, these samples in these early samples before diarrhea clustered together, whereas during diarrhea and treatment they clustered differently. And then after resolution of the diarrhea they were in an entirely different group. And so, it's likely that there's a new normal associated with this [treatment]. (May 2, 221)

This "new normal" is at both the level of the microbial body, where a new colony has been established through the FMT procedure, and at the level of the individual and social body, in that the material conditions and social phenomenology of everyday life are shaped by the changes in microbial communities. As much as normalcy cuts across scale here, from the view of microbial science, the microbial body becomes an actor in this model, where the microbial colonies that exist within the individual body are seen as materially shaping the body's capacities, particularly around eating, drinking, and excreting.

The effect of the microbial body and its relation to normalcy can also be seen in an anecdotal case presentation by University of Minnesota gastroenterologist Alex Khoruts. Khoruts is a leader in the field of experimental FMT and has been key in the technique's resurgence. His NIH presentation focused primarily on the efficacy of the treatment, but he highlighted exceptional cases where FMT was less than wholly effective, as in the following:

> In this third patient here, it was kind of interesting, around day 28…there is some expansion of proteobacteria and then there is a bigger expansion, and what happened here is a bladder infection, and actually the antibiotic was initiated a little bit after this expansion was noted….This patient did not normalize within the

> three months that we studied her afterwards, after that episode of getting bacterium and having her [urinary tract infection]. (May 3, 169)

As Khoruts points out, the microbial body is unpredictable in its effects, and although FMT proves particularly efficacious when used to treat C. diff., it is unclear what side effects it may have – and what other conditions it might interfere in the treatment of, as the microbial communities on and in the human body interact in unpredictable ways. In the case of this patient, who is diagnosed with a urinary tract infection and treated for it with antibiotics, the expectations of her progression related to the FMT treatment are disrupted by the introduction of antibiotics that affect the microbial communities of her body. As a result, she does "not normalize" as might be expected of another FMT recipient. Here, the microbial body and the individual body are brought together through the idiom of the normal, a scalar operation that runs parallel to the use of the molecular body and ideas about 'regulation,' particularly as it relates to the governable body politic.

Through the language of the speakers at the FDA hearing, 'regulation' is posited to exist at the level of cells, organs, and on the other end of the scale, institutions like the FDA and hospital human subjects review boards. Moving between these levels of scale allow bodies to be thought of at both the molecular level, and at the level of the body politic, as 'regulation' collapses conceptions of agentive power as it relates to the body and one's ability to control bodies and their operations through deliberate governance. At the level of the molecular body, consider the Chief of the Mucosal Infection Section of the NIH, Yasmine Belkaid's, discussion of "regulatory T cells" in the human gut:

> …if you actually take some regulatory T cells that reside in the gut and if you actually look at the specificity of these T regs certain fraction of these cells actually specific for commensal antigens. So, this is a very important feature of the regulatory pathway of the GI tract. (May 2, 85)

Belkaid's description and use of 'regulation' are both molecular in their conceptions; the body is shaped by the functions of biological features like cells, hormones, and antibodies. Compare this to the conception of regulation that David Rubin, professor of medicine at the University of Chicago, presents of regulation in the gut as a crisis of broader social transformations and their impacts on the body, particularly the "hygiene hypothesis,"

> …the hygiene hypothesis postulates that the environment has become too clean, that our guts are designed to interact with our environment or to be infected or coexist with parasites in some ways and that when we're younger, we have a developmental phase in our immune system that no longer is exposed to the right things to train it to respond properly, and when we become young adults and we do get exposed to something, there's this turned-on immune response in the gut that loses its ability to regulate, and that's what we call [irritable bowel disorder]. (May 3, 85)

Rubin scales down, moving between the social management of dirt and disease to the functioning of specific bodies that have been impacted by this change in the ecology that humans are a part of; he also scales up, blaming large-scale epidemiological concerns on the changes humans have collectively made to their microbial environments. "Regulation" moves from the macro to the micro, implicating the macro for shaping the micro – but these macro level efforts are shaped by the presence of the molecular and microbial: the push towards hygiene is founded in a conception of human life as being shaped by the existence of physiological and biological forces too small for the eye to see, and too small to act upon except through similarly micro-focused mechanisms.

This move towards the regulation of society through broad governmental public health efforts points to the need to shape the institutional decision-making that may result in effects like those ascribed to the overuse of antibiotics and antibacterial soap. As Lee

Jones, the CEO of Rebiotix, makes clear, the need to regulate behaviors of individuals and institutions by other institutions is in the service of controlling the outcomes of the use of experimental procedures like FMT. For Jones, as an entrepreneur invested in the development of a 'standardized' kit to provide a reproducible and marketable product, the danger in not having regulation is something that may have negative effects both for individual bodies and capitalist efforts.

> …[R]egulations and quality standards have a very important role to play. They do two major things for all of us, they protect the patient, and because they do that, they protect the industry. This [patient-conducted FMT] is one of those things that if it runs amuck and has a disaster, it's going to be hard to recover from because people will lose faith that this is something that could be helpful. (May 3, 230)

The "quality standards" that Jones invokes is an appeal for standardization, the adoption of particular ways of producing products and experimenting with them. These quality standards are shaped by institutional regulations, but are also meant to lead to particular kinds of molecular and microbial regulation. The danger that Jones foresees is less about the individual patient and more about the corporate interests that he speaks on behalf of; the damage to a patient from an unsuccessful or harmful FMT is less important than what the mediatization of this event will have on the ability to pursue FMT as a viable, marketable treatment for C. diff. and related complaints. The need is to embrace standardization through regulation, thereby preserving the ability for medicine to act upon the body at its many conceptual scales, from the tiny microbe, to the multitudinous microbial colony, to the molar body in its social environment.

From Regular to Standard: Making the Body Normal through Capitalist Standardization

The movement from the regular to the standard is one that requires a conception of the institutionally-governed body politic as having profound effects on the behaviors of individuals, both at the level of their social interactions as well as their microbial and molecular bodies. Standardization relies on the possibility of regulation, whether on the level of biological products – like FMT treatments – or individuals, and is embedded in the processes of institutions and their determinative powers. However, the only direct control that can be exerted on a microbial community is through other microbial communities and molecular compounds, and these are inexact in their effects, which lays the basis for the unruliness of microbial communities. At its most efficacious, standardization would work across scales, normalizing a microbial community, the body it inhabits, and the medical institutions that make these effects possible. Barry Eisenstein, Senior Vice President of Scientific Affairs at Cubist Pharmaceuticals, makes this clear when he asked during the NIH-FDA workshop, "But how are you going to regulate the individual at home who calls one of the gastroenterologists and tries to get some advice? I don't understand how that works?" (May 3, 300). This question, directed at representatives of the NIH and FDA, is both a question about regulating the behavior of patients and also that of physicians and other medical professionals in a position to provide potential patients with FMT as a medical treatment. This depends, in turn, on the existence of a standard to which FMT treatments – in their composition – can be held; a non-standardized treatment, even in the hands of a physician, may lead to unwelcome outcomes. What follows is the implication that pharmaceutical companies might provide a means to make the lives of both medical professionals and patients easier by providing a standardized mechanism to produce a desired outcome. This depends upon making

FMT a viable treatment as well as making human fecal material something that can be considered a product that can be regulated and standardized, an effort that depends upon the FDA and its classification of biological materials suitable for therapeutic use.

The central standardization problem for the FDA is what FMT – and human feces in particular – count as: is feces used in the context of an FMT a drug or a biological product? To count as a biological product, the biological substance need only be modified before its introduction into another body. In both cases, it is a problem of standardizing the microbial to normalize the molar body. As Jay Slater, the Director of the Division of Bacterial, Parasitic, & Allergenic Products at the FDA explains, reading from official documentation, biological products include:

> …"a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product" – I know you were all waiting to see where fecal material fit in – "or analogous product, applicable to the prevention, treatment, or cure of a disease or condition in human beings."

What makes fecal material even more problematic is that it changes from day to day, from sample to sample. One donation can vary significantly from another – even from the same person – based on changes in diet and environmental exposures; there is routine variation within the microbiota represented in feces. Moreover, unlike a blood transfusion which, with appropriate screening, is seen as having no contagious influence between donor and recipient, the purpose of FMT is to make the gut of the recipient more like – if not identical to – that of the donor, a process that takes only days. As Khoruts explains "…usually three days [after the procedure] is when we have the first bowel movement that we can count on collecting. It looks virtually identical to that of the donor. And that persists." Because of these two forces – that donor microbial communities vary over time

and that they have a profound mimetic influence on the recipient – the goal expressed by many of the scientists, and made explicit by one industry representative, was to make a 'standard' kit of microbiota to establish 'normal' gut health based on a select group of proven microbial colonizers.

As Eisenstein makes clear, there are obvious rationales for the move towards an industrially-manufactured, 'standardized' FMT product. Much like Jones' statement above, Eisenstein sees the push towards industrially manufacturing FMT products as both a safety concern, but also a necessary basis for the commercialization of the procedure and related products:

> …there seems to be a continuum from the non-physician homebrew to the doc's office that is making use of non-standardized material to the more standardized medical centers, … to the industrial commercialization product, to, then later, an understanding of how we would use an artificial mixture of very well defined individual components that could be put together that for all time would then be active pharmaceutical product that would then be studied. And it seems that going from one end of the continuum to another, you're getting increasing characterization, increasing standardization, and increasing opportunity to better study and understand potency and efficacy and safety and also increasing opportunities to commercialize. (May 3, 299)

Similarly, Colleen Kelly, Assistant Professor of Medicine at Brown University, echoes the likelihood that it will be the pharmaceutical industry – not hospital-based research centers – that will lead the way towards standardization:

> I think what we're all going towards is some kind of a standardized product that's easy and safe and studies can be duplicated and results are more consistent, and I think that that's probably going to happen through industry rather than magic fairies coming down and giving us money to do it. (May 3, 291)

This push towards commercialized, mass-produced FMT products is simultaneously a push towards a normative conception of the human body and the relative ease with which

one body can be substituted for another through the mediation of a standardized product. It is precisely through the language of standardization that capitalist interests are able to control the body: medicine often traffics in conceptions of the normal that refer primarily to the individual body and its material status, but standardization depends not only upon a conception of the normal but the means to produce it through industrial processes and products, working from the microbial or molecular up to the individual body. Standardization depends upon static, reproducible outcomes that are founded in the normal but are made possible through manufacture.

As the CEO of Rebiotix, Lee Jones, explains, Rebiotix is "solving the problems of FMT by providing and developing a commercialized, standardized, ready-to-use product." Thus, rather than rely on donor networks, which often depend on kinship ties, Jones and the scientists at Rebiotix are attempting to produce a universal transplant based on the donations of five individuals. There are two problems, however. First, an audience member suggests that "what we consider as normal may not be normal hosts; normal or supposedly healthy people may not truly be healthy. They may actually become diseased very soon." That is, due to the complexity of the microbiota, what may look normal could be obscuring pending disorders, which may eventually become evident both in the donor and the recipient. Secondarily – and this is the more important point – is that the power of the microbiota is not based on one, three, or ten specific microbes, but rather the synergistic powers of the entire microbial 'community.' The goal, as Vincent Young from the University of Michigan claims, is "to restore a good community and replace a bad community." The goal is not conversion based upon lone microbial missionaries, but rather full-scale colonization, leading to the normalization of the individual body.

Conclusion

With the rise of attention to multispecies relationships in anthropology (Haraway 2008; Hartigan 2014), it is increasingly necessary to have models to conceptualize the many determinants of human health – including the microbial and molecular – and how they are framed by and shaped through everyday life and expert knowledge production. As made evident by FMT, patients, physicians, and anthropologists all need to reckon with the reality of human health in a multispecies world, particularly in relation to microbial communities that fundamentally shape the experience of individuals and ideas about normalcy. To fully apprehend how the individual body is composed, anthropologists need to attend to the sociotechnical environments that shape individual bodies, from the microbial communities humans interact with, to epigenetic determinants of health and disease, to the industrially produced diets and pharmaceuticals that shape the body in particular ways, to the symbolic and political mechanisms through which these chemical and microbial realities are apprehended.

In this article, I have focused on how scale operates in the conceptualization of the human body and its microbial determinants of health. By focusing on how scientists, physicians, entrepreneurs, and patients use idioms of normal, regular, and standard in thinking about individual bodies and the microbial colonies that inhabit these bodies – and can be used to modify other microbial communities – it becomes evident how these interlocking concepts apply to the individual body, the microbial communities that individuals host, and the industrial and medical processes that ensure particular kinds of 'normal' bodies are produced. By regulating microbial communities, bodily processes,

social interactions, and institutional practices, normative temporal expectations might be achieved; but producing normal bodies depends upon standardizing medical practices and microbial communities, which, in turn, depend upon rendering the human body as a site of colonization – albeit at the level of the microbial. By standardizing the microbial – the human body at one of its smallest scales – a normal, individual body can be achieved.

Through microbial colonization, FMT makes individuals more like each other. Rather than make individuals more like their kin or close friends, the push is towards 'standard,' 'normal' donors who provide 'good' communities to replace the 'bad' ones. There is significant commercial interest in developing 'standard' FMT kits, which moves beyond their use solely in the case of C. diff. The Rebiotix website suggests the next targets are ulcerative colitis and metabolic syndrome, and there have also been claims – as in the documentary *The Autism Enigma* (2012) – that the microbiota may be to blame for autism, as well as Type-2 diabetes. In an era of blockbuster drugs that routinely make $1 billion annually, 15,000 C. diff. patients each year is clearly not enough to support a burgeoning industry – but if one adds the many other possibilities that FMT might treat, the horizon expands significantly. Just like many other treatments, the aim is to standardize the individual to normative ideals produced in a laboratory and concretized through cultural expectations. The problem, however, is that a 'good' microbial colony varies over time – there is no standard 'good' community, but only good interactive potential, which may also be the case for human communities. This is the root of the problem for medical governance: unlike so many molecular treatments that aim to make an individual fit the demands of modern American society, and are largely predictable in their positive and negative effects, successful FMT depends upon the establishment of a

community of microbes that changes over time, is flexibly responsive to environmental changes, and has synergistic properties that exceed biomedical reductionism. As such, the colony within defies governmental logics of normalization; by extension, governance that takes as its goal the production and maintenance of normal bodies is fundamentally thwarted – there is no norm to aspire to, but only abstract potentiality (Taussig, et al. 2013) embodied in a multitudinous community of microbes. Although FMT kits might produce a 'standard' biomedical subject, even this new 'standard' is a moving target. The question that remains is whether this marks one possible end of surveillance medicine, or an opening into new regimes of control – to the extent that our microbiotic communities will tolerate governance of any sort.

Acknowledgements

My thanks are extended to Lance Gravlee and the editorial assistants at MAQ for their continued attention to this article in its manuscript form, as well as the three anonymous reviewers who reviewed this paper in its earliest version, and the two reviewers who read its more finalized form. An abbreviated version of this article was presented at the AAA meetings in 2014, and my thanks are extended to my co-panelists, Karen-Sue Taussig, Seth Messinger, and Anna Zogas, for their early reactions to the research, as well the audience members who asked provocative questions. Finally, my thanks go to Joshua Reno and Katherine Martineau, who both carefully read this article's near-final version and helped me clarify my thinking.

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[1] This paper grows out of a much larger archival and ethnographic project on the use of excrement in American medicine, as therapeutic and concern. Fieldwork is being conducted in an ongoing fashion with gastroenterologists and microbiologists concerned with the use of human microbiota as a therapeutic. Additionally, archival research is focused on the history of these therapeutics and the broader scientific, medical and political contexts of American uses of human excrement in medicine and elsewhere. The quotes included in this article are drawn from transcripts provided by the NIH for the meetings, which were transcribed by a professional transcriptionist. I have only made minor grammatical adjustments to the NIH text for ease of readability.

[2]http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Vaccines/ucm361379.htm

[3] In making this suggestion, I am adding to Nancy Scheper-Hughes and Margaret Lock's 'three bodies' concept (1987), which sees medicine as operating on the individual, social, and body politic. In making such an argument, they see medicine moving from the individual, physiological body, to the social body as a site of interaction and cultural construction, and the body as a part of a broader population, governed by biopolitical bureaucracy.

[4] I use the term 'molar' to refer to the individualized and delimited body, which draws on the work of Gilles Deleuze and Felix Guattari in their Spinozist theorization of embodiment (Deleuze and Guattari 1987 [1980]). They juxtapose this molar conception of the body to a 'molecular' one that is imperceptible, yet exerts force on the molar body and its environment in powerful ways.

[5] In many studies of medical governance, which are largely indebted to Michel Foucault's work on governmentality and disciplinary institutions (Foucault 1990 [1976]; Foucault 1994 [1963]; Foucault 1995 [1975]; Foucault 2000 [1978]), the human body is the endpoint of analysis. The human body might be a carrier of disease, but it is only through acting on the human body that disease – primarily viruses and bacteria – can be acted up. Foundational here is David Armstrong's work on 'surveillance medicine' (Armstrong 1995; Armstrong 2002), which focuses on the human body as a site of governance and subjection: medical institutions define particular kinds of individuals and behaviors as being at risk or risky, and individuals come to accept and inhabit these classifications, providing the individual with a sense of 'identity' and simultaneously providing medical institutions and the state the means to manage populations. This conception of medical governance depends upon the bureaucratic and abstractive forms of biopolitics that arose in the 19th century to oversee urban and colonial populations, which have their foundations in quantitative, statistical forms of prediction and rationalization (Hacking 1990; Porter 1986), and which focus primarily on the human body as the endpoint of analysis.