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Permalink

<https://escholarship.org/uc/item/90v7k0pp>

Journal

AJOB Empirical Bioethics, 3(3)

ISSN

2329-4515

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Publication Date

2012-07-01

DOI

10.1080/21507716.2012.662574

Peer reviewed



Published in final edited form as:

AJOB Prim Res. 2012 July 1; 3(3): 12–20. doi:10.1080/21507716.2012.662574.

Ethical Discourse about the Modification of Food for Therapeutic Purposes: How Patients with Gastrointestinal Diseases View the Good, the Bad, and the Healthy

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Abstract

Background—Researchers have the potential to utilize genetic modification (GM) technologies to create a hybrid of “food” and “medicine” that may challenge traditional understandings of what is “natural”. Moral and ethical concerns are likely to arise in any discussion of these therapeutic foods and will affect the integration of products into clinical care and daily life. This study examined how patients with chronic gastrointestinal (GI) diseases view probiotics as future bioengineered therapeutic foods.

Methods—A multi-site qualitative study consisting of focus groups with chronic GI diseases was conducted at Cleveland Clinic, Mayo Clinic, and Johns Hopkins University

Results—We conducted twenty-two focus groups with 136 patients with major GI diseases between March and August 2009. GI patients associated the term “natural” with concepts of diminished risk and morally “good”; conversely, patients associated the term “unnatural” with things that are “risky,” “foreign”, and morally “bad”. Readily available unmodified probiotics were more commonly described as “natural” while genetically modified probiotics were more commonly labeled as “unnatural” and “risky”. However, patients acknowledged that not all natural products are safe, nor are unnatural products always harmful.

Conclusions—If GI patient perspectives are indicative of public perceptions of therapeutic foods, our findings suggest that the potential benefits and risks of clinical and public health initiatives employing therapeutic foods will be understood in moralistic terms. Bioethicists and

others should be sensitive to the implicit normative appeals that are often embedded in the language of what is “natural” and “unnatural”.

Keywords

Probiotics; bioethics; empirical research; qualitative research; metagenomics

INTRODUCTION

Understandings of health and medicine often derive from deeply held cultural and moral beliefs that are reflected in the language used to characterize new therapies. In previous discussions of genetic modification (gene therapy, genetically modified (GM) foods, etc.), the rhetoric of natural/unnatural has served as a proxy for normative judgments of what is morally good/bad and safe/risky (de Boer 2009). In common parlance, “natural” tends to have positive connotations; natural entities are thought to be safer, healthier, or kinder to the environment (Rozin 2005; Holm 2003). Genetic engineering and various forms of biochemical manipulations are objectionable to many people in large part because they are associated with departures from the status quo of what is considered “natural” (Evans et al. 2010; Rozin 2005).

In contrast to public understandings of the term “natural,” in scientific discourse the term is typically used in a value-free fashion, not as a designation of what is either good or bad, nor in a way that distinguishes between laboratory work and farming or evolutionary processes (Nuffield Council on Bioethics 1999, Verhoog 2003). For scientists, events ranging from environmental disasters to pandemic viruses are “natural” phenomena amenable to study, in part with the hope of discovering ways to modify them and mitigate harm (Nuffield Council on Bioethics 1999).

As a result of advances made through the Human Microbiome Project (Turnbaugh et al. 2007, Peterson et al. 2009), researchers are now potentially merging genetic modification and gene therapy technologies to create a hybrid of “food” and “medicine” that may challenge traditional understandings of what is “natural”. Probiotics are defined as “live microorganisms which when administered in adequate amounts confer a health benefit on the host” (FAO/WHO Working Group 2002) and are similar to those found in the human gastrointestinal tract (National Center for Complementary and Alternative Medicine n.d.). Probiotics straddle conventional and regulatory distinctions between foods and drugs (Table 1), an area of overlap that Eussen and colleagues (2011) have described as the “pharm-nutrition interface”. Currently available probiotic products are consumed as *functional foods*, in the form of dietary supplements (pills) or food (yogurt) as therapy for gastrointestinal distress, genitourinary symptoms, and to support wellness. In the future, probiotics may be genetically modified for specific therapeutic purposes, though still delivered through a consumable platform, thus becoming more like *medical foods* or *pharmaceutical drugs* regulated by the FDA. In this sense, both existing probiotics and future probiotics that might be altered to enhance their therapeutic effects blur traditional distinctions between “natural” foods and “synthetic” medicines. To avoid confusions that may result from the assignment of probiotics to a specific regulatory category, we will use the term *therapeutic foods* to refer to all forms of probiotics, without making assumptions about the regulatory category to which they belong.

According to a 2009 survey of Americans, consumers are very positive about functional foods that promise health and wellness benefits, with more than 85% of those surveyed indicating that they currently are consuming or would be interested in consuming functional foods for specific health benefits (Kapsak et al. 2011). Technological advances in

therapeutic foods are most likely to be targeted toward people with certain diseases, such as gastrointestinal (GI) disease (Watson and Collins 2010, Barrett 2010, Steidler 2003, Steidler 2005). Currently, little is known about how patients view the potential impacts of these developments, despite the fact that they are likely to make up the majority of potential users of therapeutic foods. In this paper, we provide insight about what the concepts of natural and unnatural mean for GI patients in the context of food and modified therapeutic foods. We also explore the normative beliefs about the natural-unnatural distinction that GI patients bring to probiotics, genetic modification of probiotics, and the potential use of food as an innovative platform for delivering medical treatments and public health interventions.

METHODS

The results reported here are drawn from a larger qualitative research study exploring GI patient attitudes toward probiotics and GM probiotic applications. These methods are reported in more detail elsewhere (Mercer et al. 2011)

Study Design and Sample

Adult patients with chronic GI diseases for which probiotics are sometimes used as therapy were recruited for participation in focus groups. Focus group methodology uses group interaction to gather data on a specified topic of interest through the expression of a variety of personal experiences and opinions in patients' own words and is ideal for efficiently gathering in-depth data on topics that have not been extensively studied (Stewart et al. 2006, Krueger & Casey 2000).

Patients were recruited from three academic medical centers. Eligible patients included those seen at one of the three outpatient specialty clinics in the past two years, 21 years of age or older, proficient in English, able to provide informed consent, and diagnosed with a chronic GI disease for which the use of probiotics may be clinically contemplated. Multiple recruitment strategies were used. To enhance patients' comfort and promote group interaction during focus groups, we grouped patients with common disease experiences

Data Collection

Data were collected in focus groups facilitated with a structured moderator guide of open-ended questions. Each moderator began by establishing baseline familiarity with probiotics, and then provided a standard definition of probiotics to ensure patients without baseline familiarity were operating under a common understanding. In the course of this initial discussion, several topics relevant to this paper either arose spontaneously or were probed by the moderator. Probe questions included:

- When you think of the word probiotics, what things come to mind?
- What is your understanding of what probiotics do in the digestive tract?"
- What do you think in general about the use of alternative treatments for treating digestive diseases?"
- What makes them alternative?"
- What do you think the advantages or disadvantages are of an alternative treatment?"
- Scientists are working on changing the genetic makeup of microorganisms that live in our digestive tract to make genetically modified probiotics to treat digestive diseases; what are your thoughts about the genetic modification of these probiotics?"

Moderators provided participants the following definition of probiotics before discussing genetically modified probiotics:

“Our digestive tracts are home to billions of living microorganisms. Some are considered friendly and some unfriendly. Our digestive tracts function best when there is the right balance of these microorganisms. Probiotics are foods or supplements that contain large amounts of friendly bacteria that are intended to improve digestive health by helping maintain this balance.”

Genetically modified probiotics were introduced later as hypothetical entities that might be created in the future, and described using an example, such as: “Scientists might genetically modify probiotics to give people who cannot digest dairy products the ability to do so. This change might be permanent.” However, it was made clear that this was only one example of genetically modified probiotics that might hypothetically be created in the future; none of the participants had been identified as lactose intolerant by the selection criteria and thus likely to benefit from the hypothetical probiotic.

Group discussions were digitally recorded. Data collection continued until we achieved content saturation.

Data Management and Analysis

Focus group recordings were transcribed verbatim and each transcript was reviewed by a member of the research team for accuracy. Codes to categorize the text into major domains, subdomains, and categories were developed through site-specific thematic summaries, inductive methods drawn from grounded theory, and an iterative process of independent review and consensus-building meetings (Corbin & Strauss 2007). All focus group transcripts were coded independently by two data analysts using QSR NVivo 8 (QSR International Pty Ltd 2008). Standard inductive techniques were used to generate thematic interpretations of coded transcripts and SPSS 16.0 was used to calculate descriptive statistics on demographic items (Corbin & Strauss 2007, IBM Corporation 2007).

Human Subjects Protections

This research protocol and all study materials were approved by the Institutional Review Boards at each of the three study sites: Cleveland Clinic, Mayo Clinic, and Johns Hopkins School of Medicine. Written informed consent was obtained from all patients prior to focus group discussions. Patients received \$50 for their participation in the study. Patients were not identified by name in focus group transcripts.

RESULTS

Description of the Sample

We conducted twenty-two focus groups at the three study sites between March and August 2009. Group composition by patient diagnosis was as follows: 8 groups with mixed diagnoses; 8 groups with irritable bowel disorder (IBD); 3 groups with irritable bowel syndrome (IBS), 2 groups with Crohn’s disease, and 1 group of patients with ulcerative colitis. Demographic characteristics of patients are summarized in Table 2. In what follows we summarize key thematic findings related to perceived risks of natural and unnatural foods, perceived associations between probiotics, and “natural-unnatural”, and “benefit-harm” as well as GM probiotics on the continuum of “natural-unnatural” and “benefit-harm”.

Perceived risks of natural and unnatural foods

Participants in our study tended to view modern food commercially produced in the United States as likely contributors to their GI problems. Chemical fertilizers, pesticides, and chemicals added to food during processing particularly worried participants:

“I just think so much of what...is happening is because of what we are polluted with or what...has been altered in our immune system from 100 years ago. You know, when we just... grew stuff in the fields and didn't fertilize it with all sorts of things and didn't put different antibiotics in the animal feed – that kind of stuff.”

Many participants claimed that the “unnatural” additives and preservatives in food may be playing a principal role in the development of their GI disease. This theme arose in particular among participants who were born and raised outside the U.S., who described feeling much healthier in their native countries:

“I am not originally from the United States. When I travel out of country and vegetables, fruits that I eat...they are natural. That makes a huge difference... And I don't really have any problems. I don't add extra things to my diet... and I am fine.”

Feeling better outside the US was ascribed to the food being less processed and more “natural”.

Participants who voiced suspicion of “unnatural” commercially produced foods in the United States often expressed a preference for replacing such items in their diet with “natural” or organically grown foods. However, one participant pointed out:

“I think the problem is for most of us, even if you grow or buy organic vegetables, we can't eat the organic vegetables. No matter whether it is organic or not, we still can't eat it.”

By virtue of the nature of the disease they live with, GI patients are suspicious about any foods they consume as having the potential to trigger symptoms; their unwillingness to eat these vegetables is disease-related.

Despite general agreement that processed foods exacerbate their symptoms, participants varied in the degree to which they perceive “natural” foods as *good* or *acceptable*. Among those participants who highlighted the benefits, these were intangible – natural foods were just “better”:

“I think when you eat natural stuff you just think, like you hear organic or you hear natural and you're just kind of taught that would be better for you than an artificial type”.

Other individuals specified that “natural foods” were beneficial because they caused fewer side effects:

“I think if you go with something natural, you think that because it is out there in the environment naturally, it is not going to have a lot of side effects. It is not something man-made with a lot of different chemicals that you don't know about.”

In contrast, some participants cautioned that even so called natural substances can cause harm when they disrupt the body's internal balance:

“...there are things that are poisonous that are natural... there are mushrooms that are poisonous...arsenic is natural!...Natural that causes no harm or unbalance is what you want.”

These quotes illustrate the nuanced evaluations that some participants made regarding food substances, even those that they considered “natural”.

Yet participants generally expressed greater wariness about the potential risks of consuming “unnatural” synthetic food products. One participant referred to them as

“...something that’s based on chemicals that are made outside of my body, outside of something that’s naturally occurring in nature, plant life, animal life. It’s something that’s synthesized; it’s something that then gets introduced to your body and has a certain effect.”

In other words, “unnatural” foods were considered to be *other*, or abnormal, and associated with “*strange side effects*”.

Genetically modified food products were similarly labeled as “unnatural”:

“If you change your DNA, the genetics of it, it’s not natural anymore.”

Participants’ comments included undertones of fear:

“Genetically modified – to me the first word that comes to mind is mutation” or “I don’t like it, it just scares me! I find it horrifying. It’s like a horror film.”

For these individuals, genetic modification and fear of the risks of “unnatural” products were closely linked. However, a substantial portion of participants implied that the “unnaturalness” of genetic modification was not as harmful as other types of modification – “*changing DNA does not add chemicals*” – and that historically, as a culture, we have always modified food; genetic modification did not seem too much more extreme.

Perceived associations between probiotics and “natural” and “beneficial”

As occurred in the discussion of food (genetically modified or otherwise), participants also linked concepts of “natural-unnatural” and “benefit-harm” in their discourse about probiotics. Probiotics were most commonly described as “natural” or “normal” and beneficial or less harmful, usually because they already exist in the human body:

“It is bacteria that normally does exist in you – it’s just a bigger dose.”

The characterizations of “natural” and “beneficial” were closely tied as a result of the perceived role of probiotics in the function of the GI tract. Participants described them as products that promote normal functioning:

“Something that helps your digestive system do what it’s supposed to do, naturally”;

sometimes by replacing bacteria that has been lost:

“Natural biotics that, if you are missing from your body, if you take this yogurt or whatever that it has, it is supposed to help”;

or in other words:

“... it is part of what your body is, it is just what maybe you’ve lost and you can get back.”

In a population of patients defined by frequent departures from “normal” GI function, probiotics were seen as a replacement for the lack of bacteria that participants thought were contributing to their disease.

At other times probiotics were defined as “natural” in contrast to what they were not; probiotics are live organisms that provide benefit, not chemicals or chemical food additives

that cause harm. Benefits from probiotics were attributed to their “natural” function in the body:

“Probiotics is trying to do something natural with the microorganisms that is already in our body, well should be in our body, but [isn’t] because of what they are doing to the food...chemically enhancing, which is worse”

or their “natural” ingredients:

“It doesn’t have any of the artificial stuff in it”,

or

“It’s not synthetic chemicals put together.”

Probiotics were perceived as more natural, more beneficial, and less risky than medications or synthetics:

“It’s natural so it doesn’t really scare me as much as medications scare me.”

Non-modified (i.e. “naturally occurring”) probiotics also tended to engender less fear in comparison to GM probiotics.

Not all participants perceived probiotics as “natural”. Among those who were more wary of probiotics, a concern about the “foreignness” of the products pervaded their comments. They viewed foreign substances as unnatural because such substances are unfamiliar to our bodies and therefore potentially harmful:

“I kinda see it as you are putting something foreign into the body. Now, maybe they’re supposed to be there, but the first thing I think of is you’re putting crazy little things in you to, hopefully, offset what’s not going right in the body. So, I kind of think of it as foreign more than normal or natural.”

Another participant summarized the potential basis for probiotics to be designated as “foreign”:

“Bacteria maybe just has a negative connotation cause it usually causes problems. And I know we have good bacteria in our bodies...but there’s something weird about putting lots of something living and foreign in the body”.

Just because a person knows intellectually that they may already have bacteria in their body does not mean they feel that adding more [bacteria] is safe or “natural”.

Unintended adverse consequences were described as a potential harm resulting from probiotics, regardless of whether they were viewed as “natural” or “unnatural”. Participants highlighted the importance of maintaining balance in the body, and raised concerns about the possibility of probiotics causing harm by upsetting that balance:

“I know there’s living organisms in the body working all the time. Every action has a reaction and... my first concern would be, you put something in there with the intent to do one thing...so probably my biggest concern would be well, what [are] these organisms gonna do [that is] not intended.”

Potential imbalances could be exacerbated if probiotics interact with other medications:

“If you don’t know what you are taking and you have certain other medical conditions...you shouldn’t be taking that stuff [probiotics] because certain things can damage and aggravate other stuff.”

Even a “natural” substance introduced unnaturally could behave in ways that are unpredictable and difficult to control or manage:

“...one of my worries about...probiotics is, will the body get reliant on artificial ingestion of organism “X” vs. producing itself or letting it naturally – you know will all of a sudden be this dependency, like you must artificially supplement this organism because now this other one isn’t there as much as it used to be. So do you now have to put a little bit more of that in you because you just wiped out a little bit of something you didn’t want to wipe out. Does it end up snowballing?”

In other words, any substance introduced into the body could potentially cause harm in the long term, whether “natural” or “unnatural”.

Having examined participants’ perceptions of probiotics, we turned to an exploration of their views about genetically-modified probiotics.

GM probiotics on the continuums of “natural-unnatural” and “beneficial-harmful”

Participant opinions of GM probiotics were consistent with their discussions of natural/unnatural and GM foods as an example of unnatural foods. Several participants were unsure how they felt about GM probiotics; these individuals asked many questions about the process and purpose of genetic modification of probiotics:

“Just because man alters it doesn’t necessarily make it bad, but it doesn’t always make it good...I’m not scared of genetically altered food or medicines, but I’d still have the same caution...especially when it’s early-on. What does it mean? What is it doing? What are the unintended consequences? So, I wouldn’t be against it, I would just have the same caution and want to know if it was safe and working – just like anything. But, I wouldn’t be adverse just because it’s genetically modified.”

Factors that would affect their opinion of GM probiotics included the nature of genetic modification as well as the safety, efficacy, mechanism of action, and side effects of the final product.

Among those who expressed an opinion about GM probiotics, the most common view was that probiotics were “natural” but that genetic modification increased the “unnaturalness” and risk of harm:

“The natural ones...are like you know, substances that we’ve been exposed to for a millennia, if not longer. Whereas this [GM probiotics] is like a totally new agent that we’re getting introduced to.”

For such individuals, GM probiotics might be akin to pharmaceuticals in their unnaturalness and foreignness:

“Before when it was natural, it occurred naturally and we had it in us anyway and now you are talking about a drug really. Putting something else that is not normally in you in you.”

The permanence of genetic manipulation contributed to conceptions of GM probiotics as unnatural and risky:

“When you start taking probiotics that have been genetically modified, that... science has warped them in such a way...that alter the composition of our bodies for a permanent time. I just feel like that’s so unnatural that I would be wary of doing that.”

Participants who focused on the unnaturalness of GM probiotics often worried about the risks posed:

“I feel that when you start messing with molecules and moving stuff around, there’s a lot more of a chance that when you take them, there will be adverse effects.”

As a whole, participants who viewed GM probiotics as “unnatural” generally also associated them with higher risks of long term, potentially harmful, effects.

Another group of participants focused on whether GM probiotics were good or bad (rather than natural/unnatural) based on the intent of their creation. If participants imagined that GM probiotics offered more therapeutic benefit than what presently existed in their gut or probiotics currently offered in stores, they were positively inclined toward the GM probiotics regardless of their natural or unnatural designation. For example:

“If they found that genetically modifying bacteria was helping people more than just what is naturally occurring in the bacteria, I don’t think that’s for evil. I think that’s for good. And I’m okay with that.”

Another participant expressed the view that GM probiotics were meant to increase the natural therapeutic effect of probiotics with the intent “*to be more natural and to get off of the dependency of some of the pharmaceuticals*”. Judgments about the acceptability of GM probiotics arose out of the context of current risks they associated with their chronic disease and its management.

DISCUSSION

We observed that many GI patients have complex and nuanced views of the natural-unnatural continuum that is reflected in how they discuss therapeutic foods. This natural/unnatural terminology arose spontaneously in focus group discussions, rather than being introduced by moderators. These discussions highlight the ways in which seemingly straightforward language can be laden with rich normative content that may go unnoticed in everyday discourse. These findings highlight the moral valences within the discourse around modified foods, particularly those like probiotics that are used for therapeutic purposes. Moral valences are implicit evaluative claims – judgments or beliefs – that convey a judgment of goodness or badness in “ordinary” descriptive terms.

Discussions among participants indicated that GI patients closely associate the term “natural”, with judgments about what is “safe” and what is not, as well as moral beliefs about what is “good”. Conversely, patients tended to associate things they label as “unnatural” with the terms “risky” and “foreign”, as well as with moral judgments about what is “bad” or ought not be manipulated by humans. While currently available probiotics were considered more “natural” than GM probiotics, they were sometimes characterized as “foreign”. This characterization may stem from a historical view of bacteria as “bad”, harmful, or disease causing. The strength of the appeal of something “natural” varied among participants, who acknowledged that not all natural products are safe, nor are unnatural products always harmful. Nevertheless, the general preference expressed for natural products echoes the recent local and organic food movements and the parallel dichotomy between organic (good) and nonorganic or pesticide-laden or processed (bad) food choices (Lockie 2006).

A strong preference for what is considered “natural” among the general public has been well documented by researchers, who concluded that this preference is moral and aesthetic (ideational) rather than related to the effectiveness of the product in improving health (instrumental) (Rozin et al. 2004). Others have claimed that the construct of “natural” is not only ideational but also aspirational – a way to avoid emotional reactions of disgust that stem from intuitions about protecting the purity of the body (Douglas 2002). As a value that

emanates from the evolutionary need to protect the body from toxins, parasites, or bacteria, (Horberg et al. 2009) this moral domain of purity can influence moral judgments about which changes to our environment are good and bad (Schnall et al. 2008). These connotations of the term “natural” are consistent with our findings about how patients view modifications to therapeutic foods. Our findings suggest that GI patients’ preferences for foods that are “natural” are complex, reflecting ideational, instrumental, and aspirational concerns about both health benefits and concepts of purity.

Perceived Risks of Probiotics and the Concept of Natural

As bacteria are shedding their historically negative associations with what is dirty or harmful, and are increasingly reconceptualized as “natural” organisms, patients appear to be viewing GM probiotics as artificial products that elicit emotional disgust and result in moral judgments that these products are “unnatural” and potentially harmful. These emotional responses are likely affected by perceptions of the risk of both conventional and GM probiotics. Research indicates that risk perception is mediated by larger cultural worldviews, moral values, and social roles (Kahan et al. 2007, Kahan et al. 2009, Kahan 2010). However, the degree to which people’s values and roles affect their perceptions of the risks of therapeutic foods has not been well studied to date (Kahan 2010).

A plausible hypothesis is that people whose GI systems are vulnerable are more likely to worry about body boundaries and their violations – in other words, that those individuals with more severe disease are more sensitive to their exposure to what they consider to be impure or unnatural foods. In light of the rich literature on disgust and purity (Douglas 2002), future work by medical anthropologists and bioethicists should explore the relationship between severity of GI disease, individuals’ reactions to probiotics, and beliefs about what is “unnatural” or “foreign”. These relationships between disease severity and conceptions of natural/unnatural may be expressed differently in people with chronic diseases who tend to have higher levels of modern day worries – concerns about how elements of modern day life such as genetically modified food, pesticides, vaccinations, or cell phones affect individual health (Petrie et al. 2001). Indeed, research has found a significant association between higher levels of modern day worries and higher reported consumption of organic foods, preference for natural food additives, and acceptance of functional foods (Devcich et al. 2007). With regard to our findings, it is plausible that individuals with GI disease may also have higher levels of modern day worries and stronger preferences for “natural” foods than individuals without GI disease.

Perceived Risks of Genetically Modified Food

Genetic modification of food typically raises a broad range of social and ethical concerns (Thompson & Hannah 2008). Prior evidence suggests the public may consider the technology ethically questionable because it tampers with nature in unacceptable ways (Myskja 2006). Moreover, the public’s negative reactions to GM food may be founded on precautionary principles (McConnon et al. 2002). Discourses about the meaning of “natural” when applied to food have prompted some scientists to dismiss public distrust of emerging scientific technologies such as genetically modified (GM) foods as merely a ‘food scare’ created and propagated by the media, and to characterize worries about genetic engineering as superficial, irrational, and ignorant (Cook et al. 2004, p.437, Frewer et al. 2002). In addition, evidence suggests that the cultural groups of “the public” versus “scientists” affect the risk perception of members of those groups with regards to therapeutic foods like probiotics (Kahan et al. 2009).

Our findings suggest an implicit ordering of the material world by GI patients, consistent with proper functioning, purposes, views of nature, and error-prone human interventions that

are intertwined with assumptions about which human manipulations are “right and wrong”. Research indicates that there is an association between the motivation to prevent or repair errors in dealing with natural processes and a preference for more restrictions on applications of genomic technologies (de Boer 2010), ostensibly to make changes that reduce the likelihood of bad outcomes.

If scientists are to engage the public in constructive discussions about the development of therapeutic foods, they will need to acknowledge potential differences between scientific and “lay” understandings about what is natural. Scientists should also be mindful that differences of opinion may reflect differing worldviews and acknowledge the views of the public even when contrary to scientific consensus, as they may express alternative cultural perspectives rather than scientific ignorance (Myskja 2006). Arguably, scientists’ failure to engage the public regarding what have been considered “unnatural” technologies (e.g. nuclear energy, radiation, and genetic modification) has contributed to public fear and occasionally outright rejection of new technologies. Over time many of these technologies have become commonplace, but their adoption may have been expedited (for better or worse) had public fear not become pervasive.

Food is a much more ubiquitous and personal, as well as communal part of our culture; the introduction of therapeutic modified foods could consequently be very popular, or rejected outright as too “unnatural” and risky. In order for functional foods like probiotics to reach their maximal potential, health professionals, government, and the food industry will need to work together to improve communication with the public (McConnon et al. 2002). Scientists who are developing therapeutic foods like GM probiotics ought to seek to identify differences in the worldviews of scientists and public consumers by building a common language to discuss so-called “unnatural” technologies. Language matters, and our findings can help scientists understand one group of the public’s perspective.

Limitations

Limitations of this study are related to our sample and methods of inquiry. Participants were recruited from large tertiary care hospitals in the U.S., and thus the views expressed by these patients may not be typical of other patients with chronic digestive diseases. In addition, patients who self-selected to participate in our focus groups may have greater knowledge or a more favorable attitude about probiotics in comparison to patients who chose not to participate. Finally, the focus group approach taken has inherent limitations, such as the potential to inhibit dissenting opinions and over-represent agreement. It is also possible that the way we framed probiotics and GM probiotics may have influenced the responses that respondents provided. If we had framed the products as drug-like products, for example, we may have elicited different opinions. These and other potential sources of bias were mitigated by the use of rigorous qualitative research methods including triangulation of data to establish converging themes, use of multiple study sites, and recruitment of participants with different GI diseases.

Conclusion

Food occupies a unique place in society, as a substance necessary to continued existence (daily eating), an element of social and religious rituals (both fasting and consuming particular food products as symbols), a marker of class (organic, free-range, grass-fed meat products), and as a key component in human health. Modified therapeutic food could alter and twist these roles, taking on double meanings of disease treatment and sustenance. The GI patients who participated in our focus groups demonstrated a more nuanced view of the natural/unnatural continuum than the binary opposition often portrayed in the media (Lockie 2006, Myskja 2006, Nuffield Council on Bioethics 1999, Verhoog 2003). These data support

the idea that moral and ethical concerns will be an integral part of future discussions of therapeutic foods, particularly those that have been genetically modified to enhance their therapeutic value (Knight 2009).

Our findings suggest that the potential benefits and risks of clinical and public health initiatives employing therapeutic foods will be understood in moralistic terms. In assessing public attitudes and beliefs about therapeutic foods, bioethicists and others should be sensitive to the implicit normative appeals that frequently are embedded in appeals to what is “natural” and “unnatural”. As new therapeutic foods are created and taxpayer dollars are invested in researching their use, it will be important to explore the moral valences underlying scientists’ and laypeople’s discourse about such products. Moreover, future research should characterize the size and significance of gaps between those two perspectives, and the impact of moral language on the public’s willingness to use such products.

Acknowledgments

This work was funded by grant number R01HG004877 from the National Human Genome Research Institute. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Human Genome Research Institute or the National Institutes of Health. We appreciate Drs. Jean-Paul Achkars’, Edward Loftus’, Gerard Mullins’, Katherine James’, and Jennifer McCormick’s contributions to the study. We thank the study volunteers who generously gave their time to share their experiences and opinions with us.

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Table 1

Conventional and Regulatory Categories of Foods and Drugs

Term	Definition	Source
Dietary supplements (informally known as "nutraceuticals")	Dietary ingredients including vitamins, minerals, herbs, botanicals, amino acids, or other "dietary substance[s] for use by man to supplement the diet" and intended for ingestion in pill, capsule, tablet, or liquid form, and is not the sole item of a meal or diet.	FDA legal regulatory definition; 21 USC 231
Functional foods	Consumed "whole foods and fortified, enriched, or enhanced foods [that] have a potentially beneficial effect on health when consumed as part of a varied diet on a regular basis, at effective levels." (Hasler & Brown 2009)	Not legal or regulatory but defined by dietitians
Modified foods	Foods "modified through fortification, enrichment, or enhancement...[e.g.] calcium-fortified orange juice (for bone health [and] folate-enriched breads (for proper fetal development)". (Hasler & Brown 2009)	Not legal or regulatory but defined by dietitians
Medical foods	"[A] food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation."	FDA legal regulatory definition; 21 USC 360ee(b)(3)
Pharmaceutical Drugs	Products intended as "(a) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease...and (b) articles (other than food) intended to affect the structure or any function of the body of man or other animals".	FDA legal regulatory definition; (§201(p)(1) [21 USC 321(p)(1)] n.d.)

Table 2

Characteristics of 136 patients participating in focus groups examining translational applications of human microbiome research.

Age mean ± SD years (range)	48 ± 16 (21–88)
	n (%)
Gender	
Female	91 (67)
Male	45 (33)
Education	
Less than high school	3 (2)
High school/GED	23 (17)
Community college	34 (25)
Four-year college	43 (32)
Graduate school	28 (21)
Professional school	5 (4)
Income*	
Less than \$15,000	11 (8)
\$15,001–35,000	17 (13)
\$35,001–55,000	27 (21)
\$55,001–75,000	23 (18)
\$75,001–100,000	25 (19)
Over \$100,000	28 (21)
Ethnicity*	
Non-Hispanic	127 (96)
Hispanic	5 (4)
Race*	
White or Caucasian	126 (93)
Black or African American	4 (3)
American Indian or Alaska Native	1 (1)
Asian	1 (1)
Multi-racial	3 (2)
Self-Reported Diagnosis*	
Crohn's Disease	47 (35)
Ulcerative Colitis	33 (24)
Pouchitis	6 (5)
Indeterminate IBD	3 (2)
Irritable Bowel Syndrome	38 (28)
Other/unknown diagnosis**	8 (6)

Health Insurance *	
Yes	128 (96)
No	6 (4)
Previous participation in research *	
Yes	64 (47)
No	71 (53)

* Not all patients provided this information.

** Two patients reported a diagnosis of small intestinal bacterial overgrowth and one reported a diagnosis of *Clostridium difficile*. Five patients reported no diagnosis to date.