HHS Public Access

Author manuscript

Food Ethics. Author manuscript; available in PMC 2019 December 01.

Published in final edited form as:

Food Ethics. 2018 December ; 2(1): 1–16. doi:10.1007/s41055-017-0023-3.

Proportionality in Public Health Regulation: The Case of Dietary Supplements

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Abstract

The idea that the degree of infringement public health interventions have on individual rights should be proportional to the degree of expected benefits has emerged as an influential principle in public health ethics and policy. While proportionality makes sense in theory, it may be difficult to implement in practice, due to the inherent conflict between individual rights and the common good underlying the principle. To apply the proportionality principle to a decision of policy, one must still find a reasonable way of balancing these competing values in light of the available options and empirical evidence. In this article, I consider how the proportionality principle applies to the regulation of dietary supplements and examine some critiques of the current oversight system. I argue that it may be difficult maintain proportional oversight because the risks of dietary supplements vary considerably. Strengthening the regulations may therefore promote an appropriate level of regulation in some cases but lead to overregulation in others.

Keywords

dietary supplements; public health; safety; regulation; proportionality; ethics; consumer choice

Introduction

The idea that the degree of infringement that public health interventions have on individual rights should be proportional to the degree of expected benefits has emerged as an influential principle in public health ethics and policy (Childress et al. 2002, Faden and Shebeya 2015; Kass 2001; Lee 2012; Nuffield Council on Bioethics 2007; Schröder-Bäck et al. 2014). The proportionality principle implies, for example, that interventions which significantly restrict individual rights to liberty or autonomy, such as mandated drug treatment of individuals with infectious diseases, are justified only if they are expected to produce substantial public health benefits, such as preventing the transmission of deadly pathogens, and other methods of producing these results are not as effective. Interventions that do not significantly interfere with individual rights, such as nutritional labelling requirements for foods, can be justified when the expected public health benefits are not as substantial. Proportionality can

Conflict of Interest

The author has no conflicts of interest to disclose.

also be viewed as a way of achieving a balance between underregulation and overregulation (Mendeloff 1981, Young 2014). A policy underregulates an activity if it does not secure adequate public benefits, given the risks of the activity; conversely, a policy over-regulates an activity if it improperly restricts liberty, autonomy, or other individual rights, given the risks of the activity.

The chief appeal of the proportionality principle is that it can provide a practical and reasonable way of resolving the conflict between individual rights and the common good which often arises in public health ethics and policy (Buchanan 2008; Dawson 2011; Gostin 2007; Holland 2015). For example, the World Health Organization (2007) appeals to proportionality to justify isolation and quarantine to prevent influenza pandemics, Ottenberg et al. (2011) use the principle to justify mandatory influenza vaccination for health care workers, and Singer et al. (2003) apply the principle to the management of severe acute respiratory syndrome (SARS).

While the notion of proportionality makes sense in theory, it may be difficult to implement in practice, due to the inherent conflict between individual rights and the common good underlying the principle. To apply the principle to a decision of policy, one must still find a reasonable way of balancing these competing values in light of the available options and empirical evidence concerning the effectiveness of different methods of securing public health (Holland 2015). For example, in the US, the Food and Drug Administration (FDA) regulates dietary supplements under the authority of the Dietary Supplement Health and Education Act (DSHEA); other countries have similar legislation (Gershwin et al. 2010). Although the DSHEA has greatly increased government oversight of dietary supplements in the US, some argue that the law does not do enough to promote public health and safety and that additional federal, state, or local regulations are needed (Cohen 2009; Dodge 2016; Fontanarosa et al. 2003; Gershwin et al. 2010; Jiang 2009; Marcus and Grollman 2002; Morrow 2008; New York Task Force on Life and Law 2005; Starr 2015, 2016). Others argue that the current regulations are more than adequate and that the best way to promote public health is to enforce existing rules and support additional research and education on the safety and efficacy of dietary supplements (Abdel-Ramen et al. 2011; Frankos et al. 2010; MacKay 2015; McGuffin 2008).

In this article, I consider how the proportionality principle applies to the regulation of dietary supplements. I provide an overview of the federal regulation of dietary supplements in the US and describe some criticisms of the current oversight system and proposed solutions. I argue that it may be difficult to maintain proportional oversight because the risks of dietary supplements vary considerably. Strengthening the regulations may therefore promote an appropriate level of regulation in some cases but lead to overregulation in others.

An Overview of Dietary Supplement Use

The use of dietary supplements, such as vitamins, minerals, and herbal medicines, has increased dramatically in the US in the last thirty years. The number of different dietary supplement products sold in America has expanded from about 4000 in 1994 to over 90,000 today (Starr 2015). An estimated 52% of US adults regularly consume dietary supplements,

spending $37 billion annually on these products (Bradley 2015; Kantor et al. 2016). According to industry data, the dietary supplement business has a $122 billion impact on the US economy and employs 383,230 workers (Council for Responsible Nutrition 2016a). While many consumers (85%) take vitamin or mineral supplements (Gershwin et al. 2010). The use of herbals increased from 2.5% to 12.1% from 1990 to 1997 (Eisenberg et al. 1998). US consumers use dietary supplements to improve their physical or mental health, lose weight, treat symptoms, enhance athletic or sexual performance; and as an alternative to drugs available by prescription or over-the-counter (Starr 2015).

Most consumers claim to derive significant benefits from dietary supplements, but evidence for health claims made by these products is often lacking (Dodge 2016; Starr 2016). Although some supplements, such as Vitamin D, Vitamin B6, Vitamin B 12, and folic acid, have scientifically proven health benefits, most others do not (Church et al. 2015; Gershwin et al. 2010; Office of Dietary Supplements 2016a, 2016b; Shanahan and de Lorimier 2013). Moreover, many supplements can pose serious risks to consumers (Starr 2015). Some of these products can cause kidney or liver damage, increase the risk of cancer, adversely interact with medications, induce toxicity at high doses, or contain contaminants, such as drugs (Bent et al. 2005; Cohen 2009; Ernst 1998; Gershwin et al. 2010; Haller et al. 2008; Hu et al. 2005, Jiang 2009; National Toxicology Program 2016; Starr 2015).

Based on an analysis of 3667 cases, Geller et al. (2015) estimated that adverse events (AEs) related to dietary supplements result in 23,005 emergency room (ER) visits per year in the US, leading to 2154 hospitalizations. The most common reasons for ER visits included cardiovascular problems related to use of weight loss or energy products by young adults and swallowing or choking by older adults. The study did not estimate the number of deaths due to variations in reporting practices by hospitals (Geller et al. 2015). By comparison, drug AEs account for about 1.3 million ER visits per year in the US (Shehab et al. 2016).

Some supplements contain chemicals that are classified as drugs when marketed in a purified form. For example, red yeast rice contains monacolin K, which is chemically the same as an active ingredient in the drug lovastatin, which the FDA has approved for lowering blood cholesterol levels (National Center for Complementary and Integrative Medicine 2016). While patients with high cholesterol can benefit from taking drugs containing statins, some patients may experience serious side-effects from these medications, such as muscle pain and weakness, liver damage, diabetes, and memory loss (Mayo Clinic 2016).

In the 1990s, supplements containing ephedrine alkaloids, such as the product known as Ephedra, were implicated in numerous AEs and serious adverse events (SAEs), including heart palpitations, tachycardia, seizures, stroke, and death in at least ten cases (Haller and Benowitz 2000). Ephedrine alkaloids are chemically related to the bronchodilating drugs ephedrine and pseudoephedrine, which can help relieve the symptoms of allergies, asthma, and respiratory infections, but also increase blood pressure and heart rate. The FDA issued warnings about ephedrine alkaloids in 1994, and by 1997 the agency had received over 800 AE reports related to Ephedra. The agency continued to issue warnings concerning products

containing ephedrine alkaloids and finally banned them in 2004 (New York Task Force on Life and Law 2005).

The Regulation of Dietary Supplements in the US

Dietary supplements occupy an awkward place in the US regulatory landscape, somewhere between drugs, which are heavily regulated, and foods, which are not. In 1938, the US Congress passed the Food, Drug, and Cosmetics Act (FDCA), which gave the FDA authority to regulate commercial products classified as foods, drugs, or cosmetics. The FDCA treats foods and drugs very differently. The FDA defines a drug as:

> A substance recognized by an official pharmacopoeia or formulary.
>
> A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.
>
> A substance (other than food) intended to affect the structure or any function of the body.
>
> A substance intended for use as a component of a medicine but not a device or a component, part or accessory of a device.
>
> Biological products are included within this definition and are generally covered by the same laws and regulations, but differences exist regarding their manufacturing processes (chemical process versus biological process (Food and Drug Administration 2017).

To obtain FDA approval to market a new drug, a manufacturer must provide the agency with evidence of safety and efficacy from animal studies and three phases of clinical trials involving human subjects (Gassman et al. 2017). The manufacturer must also submit data to the FDA concerning its good manufacturing practices (GMPs) for making the drug and its ability to implement those practices. Once the drug is on the market, the manufacturer is required to promptly report any AEs associated with the drug to the FDA, and the agency may also require the company to do additional research related to safety and efficacy (Gassman et al. 2017). The FDA also has the authority to regulate labelling and advertising, issue safety warnings, and withdraw market approval to protect public health (Daemmrich 2004). The FDA's regulation of food additives (such as artificial sweeteners, preservatives, and dyes) also involves pre-market safety testing, manufacturing requirements, appropriate labelling, and post-market surveillance (Fortin 2016).

The FDA's regulatory decisions concerning the availability of drugs to consumers reflect a proportionality policy (Daemmrich 2004; Gassman et al. 2017). The FDA will not approve a drug if it determines that its risks outweigh its benefits. The impact of this policy is that high-risk drugs will be kept off the market unless they are also likely to yield significant benefits; for example, the FDA may approve highly toxic chemotherapy drugs if they can treat cancer effectively. The FDA may issue warnings or withdraw approval from a drug if significant risks materialize after it is on the market. The FDA may allow a drug to be available only by means of a prescription if it determines that the drug offers significant benefits, but that it is too dangerous to be available without supervision by a physician (or

another health care professional). Alternatively, the FDA may allow a drug to be sold over-the-counter if it determines that the drug is safe enough to be used without supervision by a physician (Gassman et al. 2017).

Almost since its inception, the FDA has faced challenges to its proportionality policy from opposing sides. While public health advocates have argued that the agency underregulates products, others have argued that it overregulates products (Hawthorne 2005; Miller 2000). In the 1980s and 1990s, activists argued that the agency was preventing HIV/AIDS patients from obtaining access to potentially life-saving, experimental medications. They urged the FDA to relax its review standards and make drugs widely available to terminally-ill patients after Phase I safety testing (Schüklenk 2000). More recently, some physicians, patients, and policy analysts have objected to the FDA's decision in 2013 to classify fecal transplants as drugs (Smith et al. 2014; Young 2014). In the US and other countries, physicians have transplanted fecal matter from healthy volunteers into patients with gastrointestinal diseases. Some studies have shown that this procedure is 90% effective at treating *Clostridium difficile* infections (Kassam et al. 2013). Classifying fecal matter as a drug requires physicians who want to conduct fecal matter transplants to submit an investigational new drug (IND) application to the FDA and obtain approval for clinical trials before administering the treatment to patients. Physicians have complained that they do not have the time or resources to submit an IND application and that the FDA's decision interferes with medical practice (Smith et al. 2014). In 2014, the FDA reversed its position on fecal matter after hearing testimony from physicians and representatives from the Centers for Diseases Control and Prevention and several medical organizations (Smith et al. 2014).

New food products that are not classified as food additives or dietary supplements can be marketed in the US without prior FDA approval, although the FDA can regulate products once they have been marketed (Fortin 2016). For example, the FDA can issue recalls for products that have been contaminated or adulterated, issue safety alerts to protect the public, inspect canned or packaged foods and fruits or vegetables, and fine companies for non-compliance (Fortin 2016). State and local laws, as well as US Department of Agriculture (USDA) regulations, also apply to foods. For example, local health departments grant licenses to commercial food establishments, require them to comply with food and beverage regulations, and conduct regular health inspections to monitor food safety and quality and regulatory compliance (Resnik 2015). The USDA inspects meat, poultry, and eggs for safety and quality and can require products to be taken off the market that fail inspection. The USDA may also issue regulations and guidelines and fine companies for non-compliance (Fortin 2016).

The FDA initially attempted to regulate some dietary supplements by treating them as drugs, based on their potency or health claims stated on their labels. However, manufacturers mounted successful legal challenges to this strategy and Congress passed legislation in 1976 prohibiting the FDA from treating dietary supplements as drugs (Gershwin et al. 2010). After failing to regulate dietary supplements as drugs, the FDA tried to regulate them as food additives, but the courts also ruled against this interpretation of the FDCA (Gershwin et al. 2010).

In 1990, Congress passed the Nutrition Labelling and Education Act (NLEA), which required that all packaged foods (including dietary supplements) provide nutrient information on the label. The NLEA also gave the FDA the authority to regulate health claims made by food products (Gershwin et al. 2010). In accordance with NLEA, the FDA established standards for evaluating and approving health claims. Congress passed the Dietary Supplement Act (DSA) in 1992 in response to the FDA's rejection of most health claims made for dietary supplements. The FDA proposed rules under the DSA that would have limited the potency of vitamins and minerals and classified some herbal products as drugs or food additives. The ensuing debate about the FDA's authority to regulate dietary supplements led to passage of the DSHEA in 1994. The DSHEA was amended in 1997 and 2006 (Gershwin et al. 2010).

The Dietary Supplement Health and Education Act

The DHSEA gives the FDA wide-ranging authority to regulate dietary supplements. The current version of the DSHEA defines a dietary supplement as:

> **(1)** …[A] product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:
>
> **(A)** a vitamin;
>
> **(B)** a mineral;
>
> **(C)** an herb or other botanical;
>
> **(D)** an amino acid;
>
> **(E)** a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
>
> **(F)** a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E) (Dietary Supplement Health and Education Act 1994: Section 3a).

The DSHEA excludes drugs and food additives from the definition of dietary supplement (Gershwin et al. 2010).

The DSHEA gives the FDA the authority to take action against supplement manufacturers (such as issuing warnings, banning, or restricting products) if one of their products presents a "significant or unreasonable risk of illness or injury" when used as recommended; poses an "imminent hazard to public health or safety"; is a new dietary ingredient for which there is inadequate safety information; or has been adulterated (Dietary Supplement Health and Education Act 1994: Sections 4a-4d). The burden of proof falls on the FDA to demonstrate that a product meets one of these conditions before taking action against a manufacturer.

Although the FDA has considerable authority to regulate products that are on the market, its pre-market authority is somewhat limited. Manufacturers of new dietary ingredients must provide the FDA with evidence that their products only contain ingredients that are present in the food supply, have not been chemically altered, or are reasonably expected to be safe.

This standard of evidence falls short of the FDA's standard for approving new drugs in that it does not require manufacturers to produce safety data from clinical trials or proof of efficacy (Starr 2015). Moreover, "new dietary ingredients" does not include ingredients that were sold in the US before October 15, 1994 (Dietary Supplement Health and Education Act 1994: Section 8). Thus, the DSHEA grandfathered in thousands of products that were already on the market when the legislation was passed (Starr 2015).

The DSHEA also gives the FDA the authority to regulate labelling of dietary supplements. Labels must state the ingredients in the supplement, including quantities. Labels may include claims related to nutritional support or structure-function relationships (Dietary Supplement Health and Education Act 1994: Section 6–7); e.g. "product x provides nutritional support for the immune system" or "product x aids in metabolism." However, statements of nutritional support or structure-function relationships must be accompanied by a disclaimer informing the consumer that "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease (Dietary Supplement Health and Education Act 1994: Section 6c)." The FDA works with the Federal Trade Commission (FTC) to ensure that dietary supplement labelling does not include false or misleading information (Starr 2015).

The DSHEA also authorizes the FDA to develop standards for quality assurance for dietary supplements (i.e. GMPs) to ensure that products sold to consumers contain the ingredients in stated quantities, do not contain contaminants or unapproved ingredients (such as drugs), and are appropriately labelled and packaged. In 2007, the FDA published quality assurance guidelines for industry (Starr 2015).

As originally drafted, the DSHEA included no AE reporting requirements for manufacturers. However, in 2006, the Dietary Supplement and Nonprescription Drug Consumer Protection Act amended the DSHEA to require that dietary supplement manufacturers, packers, and distributors submit SAE reports they receive to the FDA's Center for Food Safety and Applied Nutrition (Gershwin et al. 2010). An SAE is an event that results in: death, a life-threatening condition, hospitalization (or prolongation of a hospital stay), disability, birth defect, or other serious medical problem requiring treatment to avoid death or permanent damage (Starr 2015).

Dietary Supplement Regulation and Proportionality

As one can see from the preceding overview of the US dietary supplement regulations, the oversight system embodies a proportionality principle because the FDA regulates dietary supplements less stringently than drugs but more stringently than foods. The guiding assumption behind this approach is that degree of oversight should reflect the degree of risk related to a product. It is therefore appropriate to treat dietary supplements differently from foods and drugs because they are generally more risky than foods but less risky than drugs (Gershwin et al. 2010).

If we apply the proportionality idea to specific regulatory decisions concerning dietary supplements, it implies that actions which significantly impinge upon consumer choices,

such as bans or marketing restrictions, should only apply to supplements that pose significant risks. The FDA's decision to ban supplements containing ephedrine alkaloids was based on its review of hundreds of SAEs related to these products. Supplements that do not impose significant risks to consumers, such as many types of vitamins and minerals, should not be banned or restricted.

The Congressional findings in DSHEA mention the importance of protecting and promoting public health as an overarching rationale for enacting the legislation but allude to the need to strike the right balance between achieving this goal and respecting consumer choices: "[A]lthough the Federal Government should take swift action against products that are unsafe or adulterated, the Federal Government should not take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers (Dietary Supplement Health and Education Act 1994: Section 2)."

Although the US has made considerable progress since the passage of the DSHEA to protect consumers from the health and safety risks associated with dietary supplements, some have argued that the regulations do not go far enough. Criticisms of the current system and reform proposals are discussed below (see Table 1 for summary).

Criticisms of the Current Oversight System and Reform Proposals

Inadequate Pre-Market Review

As noted above, the DSHEA exempts dietary supplements which were on the market before 1994 from pre-market review. However, some dietary supplements grandfathered in by the law have been associated with SAEs (Bent et al. 2005; Ernst 1998; Gershwin et al. 2010). The DSHEA articulates a safety standard for new dietary ingredients that is much weaker than the standard the FDA uses to evaluate new drugs and does not require any proof of efficacy. The FDA is in the process of drafting safety guidelines for new dietary ingredients (Starr 2015). Additionally, many manufacturers are marketing new dietary ingredients without submitting any safety information to the FDA or obtaining approval. Although the FDA has issued warning letters to dozens of companies, it is difficult for the agency to enforce its pre-market review rules for new dietary ingredients on the hundreds of companies that are breaking the law, due to limited resources for enforcing DSHEA regulations (Gershwin et al. 2010; Starr 2015).

Reform Proposals

Fontanarosa et al. (2003), Gershwin et al. (2010), Marcus and Grollman (2002), and Morrow (2008) argue that pre-market review requirements for dietary supplements should be strengthened to protect public health and safety. Gershwin et al. (2010) propose that all dietary supplements (not just new dietary ingredients) should have premarket FDA approval and that manufacturers should have to submit evidence that their products are safe when used as recommended. The burden of proof should fall on manufacturers. The New York Task Force on Life and Law (2005) and Starr (2016) suggest that states could increase their pre-market regulation of dietary supplements to protect public health and safety. However,

laws enacted by the states may be preempted by federal statutes and regulations (Starr 2016).

Problems with Adverse Event Reporting and Post-Marketing Surveillance

Although the DSHEA mandates reporting of SAEs, critics have argued that SAEs are underreported (Gershwin 2010, Starr 2015). According to the US Government Accountability Office (GAO), the FDA received 596 SAE reports and 352 mild to moderate AE reports for dietary supplements during a 10-month period in 2009, but the estimated number of AEs is probably closer to 50,000 each year. The GAO also found that 64% of reports of mild to moderate AEs should have been reported as SAEs, and that manufacturers often do not provide the FDA with enough information to make a safety determination (US Government Accountability Office 2013). Another problem with reporting is that most patients do not tell their physicians about their dietary supplement use and most physicians do not ask their patients about it (Blendon et al. 2001). The failure to communicate about dietary supplement use can prevent physicians from discovering and reporting AEs related to supplements (Gershwin et al. 2010).

Reform Proposals

Marcus and Grollman (2002) argue that dietary supplement manufacturers should be required to report all adverse events, not just SAEs. It is worth noting, however, that problems with AE reporting are not unique to dietary supplements (Institute for Safe Medication Practices 2015). To adequately deal with the AE reporting problem for dietary supplements, it may be necessary to revamp the FDA's post-market surveillance system and incentivize health care providers to recognize and report AEs related to various medical products (Fontanarosa et al. 2003, Frankos et al. 2010, Resnik 2007). Providing the FDA with additional resources could help to address deficiencies related to evaluating AEs and SAEs. Starr (2016) suggests that states could also regulate dietary supplements post-market to protect the public from dangerous products. Increasing the FDA's resources for AE evaluation and post-market surveillance could also play an important role in protecting the public (Gershwin et al. 2010).

Insufficient Post-Marketing Research

As noted above, the FDA has the authority to require manufacturers to conduct post-marketing studies of approved drugs. Post-marketing studies can help to clarify the risk/benefit profile of a drug; identify risks that were not detected or adequately characterized in pre-marketing research or adverse event reporting; and compare the safety and efficacy of different drugs (Institute of Medicine 2012). Since the DSHEA does not include a similar requirement, dietary supplement manufacturers have little motivation to sponsor post-marketing research (Starr 2015). Although several branches of the National Institutes of Health (NIH 2016), including the Office of Dietary Supplements (ODS), the National Toxicology Program (2016), and the National Cancer Institute, fund studies on dietary supplements, one might argue the FDA should have the authority to require manufacturers to conduct post-marketing studies (Starr 2015).

Reform Proposals

Abdel-Ramen et al. (2011), Gershwin et al. (2010), Marcus and Grollman (2002), Morrow (2008), and the New York Task Force on Life and Law (2005) have discussed the importance of conducting more research on the safety and efficacy of dietary supplements. While few people would dispute the importance of conducting research on dietary supplements, the pressing issue is who would pay for it. Government agencies have limited funds for the this types of research and manufacturers are not likely to financially support it unless they are required to by law.

Inconsistent Quality Control

Poor quality control is another problem that creates risks for dietary supplement users. According to a 2010 GAO report, researchers found trace amounts of lead, cadmium, arsenic, mercury, and pesticides in 93% of 40 dietary supplement products examined (US Government Accountability Office 2010). A study by LeBlanc et al. (2013) from 15 sealed Vitamin-D supplement bottles sold in Portland, Oregon found that pills contained 52% to 135% of the expected dose. However, the pills from one manufacturer, which complied with US Pharmacopeia Convention standards, were all within 10% of the expected dose (LeBlanc et al. 2013). Newmaster et al. (2013) found that 59% of herbals tested had plant materials, which were not listed on the label, and 83% had active ingredient substitutions. Cohen et al. (2003) found that 66.7% of dietary supplements contained one or more banned drugs six months after the FDA had taken action against manufacturers for adulteration. The sheer number of manufacturers may make it difficult for the FDA to monitor quality control. One study found that in 2013 the FDA conducted GMP compliance inspections on only 2.8% of the 14,495 dietary supplement manufacturers registered with the agency. The FDA cited 65% of inspected firms for non-compliance with GMP standards (Natural Products Insider 2016). It is also worth noting that poor quality control undermines rigorous research on the benefits and risks of dietary supplements, since patients participating in studies may not receive a standard dose of the active ingredient, which can make it difficult to interpret results (Starr 2015).

Reform Proposals

Cohen (2009), Dodge (2016), Gershwin et al. (2010), and Marcus and Grollman (2002) propose that the FDA should enhance its monitoring of dietary supplement manufacturers for quality control and compliance with GMP standards. Gershwin et al. (2010) suggest that the FDA should clarify and strengthen its GMP guidance and that dietary supplement manufacturers should register with the FDA.

Misleading Labelling and Advertising

A 2003 Office of Inspector General Report found that dietary supplement labels often do not contain information concerning the purpose of using the supplement, ingredient concentrations, contraindications, drug interactions, or maximum dose. The report also found that labels are often difficult for consumers to understand (Office of Inspector General 2003). A 2010 GAO report found that manufacturers often make misleading claims concerning the benefits and risks of their supplements, despite the FTC's and FDA's effort

to prevent them from making false, deceptive, or unsubstantiated claims (US Government Accountability Office 2010). A study of dietary supplement websites found that 55% of 338 commercial sites made claims concerning diagnosis, treatment, or prevention of diseases, which the FDA regulations forbid (Morris and Avorn 2003).

Reform Proposals

Gershwin et al. (2010) propose that dietary supplement labels should include warnings about possible adverse effects and drug interactions and advise consumers to discuss their supplement use with their physicians. Dodge (2016), Fontanarosa et al. (2003), Gershwin et al. (2010), and Marcus and Grollman (2002) also propose that the FDA and FTC should increase their efforts to enforce existing laws concerning truth in advertising and appropriate supplement labelling.

Poor Consumer Understanding

Numerous studies have found that consumers often misunderstand the role of the government in ensuring the safety and efficacy of dietary supplements (Dodge 2016). A survey of 185 undergraduate students found that 50% believed erroneously that the FDA is responsible for analyzing the content of dietary supplements (Dodge et al. 2011). A survey of 3,500 US adults found that 50% overestimated the safety, efficacy, and government scrutiny of dietary supplements used for weight loss (Pillitteri et al. 2007). A review of 17 different surveys found that most consumers are not aware of the FDA-required disclaimers on supplement labels and that these disclaimers have little impact on consumers' perceptions of the safety and efficacy of dietary supplements (Kesselheim et al. 2015).

Reform Proposals

Although the word "education" is part of the Dietary Supplement Health and Education Act, the landmark legislation does not include any provisions that deal specifically with public education. The DSHEA established the ODS within NIH, but this agency focuses mostly on research, not public education (Dietary Supplement Health and Education Act 1994: Section 13). Various authors have proposed that educating the public on the risks, benefits, quality control, and government oversight of dietary supplements could improve consumers' understanding of these products and enable individuals to make informed choices concerning supplement use (Gershwin et al. 2010; New York Task Force on Life and Law 2005; Starr 2016).

Critiques of the Current System and Proportionality

Many of the critiques of the US' system of dietary supplement regulation could disrupt proportionality and lead to overregulation. For example if rules were adopted that require pre-market review of all dietary supplements (not just new dietary ingredients), then some types of vitamins shown to be safe and effective at preventing some types of diseases in certain populations when used as recommended could be temporarily banned, pending submission of safety data and FDA approval. In the interim period, patients lose access to products that could benefit their health, which would significantly constrain their autonomous decision-making related to dietary supplement use. Strengthening pre-market

review standards could also lead to overregulation if the FDA requires manufacturers to demonstrate efficacy, not just safety, since this could prevent consumers from purchasing benign products that they believe benefit them. Other proposed reforms, such as requiring post-marketing research or strengthening safety reporting or quality control, could constrain consumer choices by increasing the costs of dietary supplements and decreasing their affordability.

If the US regulated dietary supplements like it regulates drugs, the costs for industry and consumers could be astronomical. The average cost to develop and obtain marketing approval for a new drug in the US is estimated to be $2.56 billion. Post-marketing research and surveillance adds an additional $312 million to these costs for a total of $2.87 billion (Tufts Center for the Study of Drug Development 2016). Smaller supplement companies probably would go out of business if they had to face the type of regulatory burdens that the US imposes on drugs. Companies that do not declare bankruptcy might need to cut back on their workforce to accommodate increased costs related to regulation. Companies that remain in business would likely pass on the costs of increased regulation to consumers, which could make the prices for dietary supplements unaffordable for many.

The main reason why it may be difficult to promote public health while striving for proportionality is that the risks of dietary supplements vary considerably. Some supplements, such as red yeast rice, contain compounds which are regulated as drugs when sold in purified form. Others, such as Ephedra, have been adulterated with chemicals that are marketed as drugs. However, many supplements, such as vitamins, minerals, and amino acids, are similar to foods in terms of their (low) risk profile. While proportionality may imply that some supplements should be regulated like drugs, it may not have the same implication for others. Because the same regulatory framework applies to different types of supplements, regardless of their inherent or potential risks, maintaining proportionality can be difficult. Proposals to strengthen the regulations may help to promote an appropriate level of regulation in some cases but lead to overregulation in others.

One way of addressing the proportionality problem would be to revise the supplement regulations to provide more stringent oversight for some types of supplements, such as those that function like drugs. However, this proposal might require a radical revision of the regulations that creates a new category of supplements, which could be politically difficult to defend in the face of objections from consumers and industry groups. Also, it might not be easy to apply this new category to new products, due to the difficulties related to determining whether a supplement functions like a drug before it goes on the market. For example, federal regulators would have had little reason to suspect that red yeast rice could function like a cholesterol-lowering drug prior to its widespread use by consumers.

Another way of addressing the proportionality problem would be to judiciously apply existing regulations to protect consumers from harm. Since the regulations give the FDA a certain amount of discretion related to the oversight of dietary supplements, the agency could use its authority to more stringently regulate products likely to impose significant risks to consumers. For example, the FDA could require some manufacturers to conduct post-marketing studies on their products to provide the agency with vital safety information,

which it could use to regulate these products. The FDA could also require manufacturers of some supplements to include additional information related to risks on labelling and increase its oversight of quality control/GMP compliance. Moves such as these would probably not dramatically increase costs to consumers because many companies are already working to improve labelling and quality control (Council for Responsible Nutrition 2016b; National Safety Foundation 2017). A survey conducted by Blendon et al. (2001) found that the American public generally supports these types of reforms.

Looking beyond issues concerning the regulation of dietary supplements, one can see difficulties with seeking proportionality with respect to other FDA-regulated products. Problems can arise because products often do not fit neatly into rigid categories like foods, food additives, drugs, biologics, cosmetics, dietary supplements, tobacco products, and so on. Thus, to implement a principle of proportionality in ethics and policy, one needs enough flexibility to adjust the degree of oversight upward or downward based on public health benefits and risks. However, regulatory flexibility may conflict with the goal of providing clarity for manufactures and consumers. Manufacturers make business decisions based on the regulatory status of their product and need to know, for example, whether a product will be treated as a food, drug, food additive, or dietary supplement. Consumers also need to how products are regulated and classified by the government agencies, so they can use this information in making purchasing decisions.

None of the foregoing need imply that proportionality is irrelevant to the regulation of dietary supplements, foods, drugs, and other consumer products, since the principle can still play a key role in guiding decision-making and policy. However, it is important realize that difficult questions related to balancing individual rights and the common good may still arise when applying the principle, and that one must still carefully consider whether a proposed public health intervention is a justified infringement on rights. The principle has usefulness as general guideline, but not as a hard and fast rule.

Conclusion

Proportionality is an influential principle in public health ethics and policy but can be challenging to implement due to tensions between the values of promoting public health and respecting individual rights. The dietary supplement regulations serve as an example of the difficulties with maintaining proportionality in the oversight of consumer products. Critics of the regulations argue that they do not do enough to protect consumers from the health and safety risks of dietary supplements, while defenders of the regulations argue that the existing oversight framework is adequate. These two reactions to the regulations highlight the value conflicts within the principle of proportionality and the complications related to navigating a course between overregulation and underregulation. It can be difficult to promote public health while striving for proportionality because the risks of dietary supplements vary considerably. Strengthening the regulations may therefore promote an appropriate level of regulation in some cases but lead to overregulation in others. Additional research on policy options related to dietary supplements may provide some useful insights into how to maintain a level of government oversight that promotes public health without inappropriately restricting individual rights.

Acknowledgments

This research was supported by the Intramural Program of the National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH). It does not represent the views of the NIEHS, NIH, or US government. I am grateful to Bruce Androphy, Mark Miller, Shepherd Schurman and Mary Wolfe for helpful comments.

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Table 1

Criticisms the US' Dietary Supplement Oversight System and Reform Proposals

Problem	Reform Proposal(s)
Inadequate Pre-Market Review	1. Require premarket review for all dietary supplements
	2. Manufacturers must submit evidence to the FDA that their products are safe when used as recommended
	3. Burden of proof should fall on manufacturers
	4. States should also regulate dietary supplements
Problems with Adverse Event Reporting and Post-Market Surveillance	1. Require manufacturers to report all AEs, not just SAEs
	2. Overhaul the FDA's post-marketing surveillance system
	3. Incentivize health-care providers to recognize and report AEs related to dietary supplements
	4. Increase the FDA's resources for post-market safety monitoring
	5. States should also monitor adverse events to protect the public from dangerous products
Insufficient Post-Marketing Research	1. Grant the FDA the authority to require dietary supplement manufacturers to conduct post-marketing safety studies
	2. Increase federal funding for research on the safety, efficacy, and quality of dietary supplements
Poor Quality Control	1. Enhance FDA monitoring of dietary supplement manufacturers for quality control and compliance with GMP standards
	2. Clarify and strengthen FDA guidance on GMP standards
	3. Supplement manufacturers should register with the FDA
Misleading Labelling and Advertising	1. Supplement labels should include warnings about possible adverse side-effects and drug interactions
	2. Supplement labels should advise consumers to discuss their supplement use with their physicians
	3. The FTC and FDA should increase their efforts to enforce existing laws concerning truth in advertising and appropriate supplement labelling
Poor Consumer Understanding	1. Increase efforts to educate the public on the risks, benefits, quality control, and government oversight of dietary supplements