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NOTE DE RECHERCHE

Regulating the Risks of Dietary Supplements: An Economic Analysis of Qualified Health Claims and Efficacy Statement Disclaimers

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ABSTRACT

Several important amendments to the US Food Drug and Cosmetics Act, enacted over the past decade, authorize dietary supplement manufacturers to make claims describing how such products may be helpful in preventing and treating disease. The Food and Drug Administration (FDA) previously limited such statements to approved drugs. Per the 1994 Dietary Supplement Health Education Act, however, so called "qualified health" and "structure/function claims" may now appear on product labels provided they are accompanied by disclaimers indicating, for example, that the FDA has determined that evidence supporting such statements is supportive, but inconclusive. Disclaimers may also indicate that such statements have not been evaluated by the FDA.

Qualified health claims and disclaimers now appear on product labels as a result of courts giving a broad interpretation to the applicability of commercial free speech doctrine to dietary supplement labels. In doing so, courts acknowledge that the regulator (FDA) may not always be an omniscient expert and that regulatory statutes never intended to prevent consumers from exposing themselves to risks of dupery or unsafe products, at the cost of preventing them from benefiting from the potential benefits (e.g. disease prevention, better health) of such products. This relatively recent shift in regulatory posture effectively redefines the role of government regulatory agencies in controlling potentially hazardous but useful products such as dietary supplements, drugs and alternative health practices.

This paper develops an economic analysis for such changes in regulatory posture. It introduces a model of social welfare that portrays dietary supplement regulation as an exchange of rights that occurs between the regulator and the consumer. The normative claim of this analysis of US dietary supplement legislation is that disclaimers and qualified health claims, contrary to popular belief within the medical profession, should be used on product labels in order to reduce informational constraints that were intended for prescription drugs. The positive claim is that dietary supplement regulation is moving in that direction and that US consumers will be in a better position to enjoy benefits of improved health. On the whole, these benefits are likely to outweigh welfare losses as a result of dietary supplements being improperly used.

Manufacturers of dietary supplements are trying to have it both ways. They claim their products are powerfully beneficial, on the one hand, but harmless on the other. To claim both makes no sense, and to claim either without trials demonstrating efficacy and safety is deceptive.[1]

I. INTRODUCTION

The explosive growth in consumption[2] and regulatory reform of dietary supplements of the past two decades has fostered much controversy over efficacy claims for dietary supplements. At the core of this debate lies a long-standing belief enshrined within medical practice, which regards drug safety and efficacy as the Holy Grail of drug R&D, but which, as the Editors of the JAMA contend, are inherently conflicting objectives.[3]

The contention that substances already present in our food supply, such as vitamins and micronutrients, whose safety is well known, can treat and prevent disease is not in itself new. What has emerged over the past few decades is an increasingly large body of scientific evidence calling into question the idea that only drugs can be useful for treating and preventing disease.[4] As a result of these developments, legal and regulatory reforms have rejected the principle that dietary supplements should be regulated as either food (i.e., marketed without therapeutic claims) or, in limited cases, as drugs (i.e., marketed with claims asserting their efficacy in treating disease).[5] Instead, specific legislative and regulatory reforms now permit supplement manufacturers to claim, without having conducted clinical trials, that such products may be helpful in maintaining good health and preventing disease.[6]

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[1] Phil B. Fontanarosa, Drummond Rennie, & Catherine D. DeAngelis, *The Need for Regulation of Dietary Supplements—Lessons From Ephedra*, 289 JAMA 1568, 1569 (2003).

[2] The FDA reports that from 1994-2000 the market size of dietary supplements grew from an initial level of $8 billion to $17 billion (annual sales). The annual growth rate between this period was between 10 and 12 percent per year. Per capita expenditures (sales in supplements) during this period grew at approximately 4% per year. Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements; Proposed Rule, 68 Fed. Reg. 12225 (2003). *See also* R. Ervin, Jacqueline D. Wright & Jocelyn Kennedy-Stephenson, *Use of Dietary Supplements in the United States 1988–94*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, CENTERS FOR DISEASE CONTROL AND PREVENTION, NATIONAL CENTER FOR HEALTH STATISTICS, SER. 11, NO. 244 at 3 (1999) (reporting that almost 40% of Americans over the age of 2 reported taking dietary supplements) (last visited March 16, 2006) <http://www.cdc.gov/nchs/data/series/sr_11/sr11_244.pdf>.

[3] *See supra* note 1, at 1569 (arguing that dietary supplements cannot blindly be assumed to be safe because if they are effective they must be composed of biologically active compounds, which can be potentially dangerous).

[4] *See* Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417 § 2 (3-5) [hereinafter *DSHEA*] (stating that, "there is a link between the ingestion of certain nutrients or dietary supplements and the prevention of chronic diseases such as cancer, heart disease, and osteoporosis…[P]reventive health measures, including education, good nutrition, and appropriate use of safe nutritional supplements will limit the incidence of chronic diseases, and reduce long-term health care expenditures"). For a review of the usefulness of functional foods in preventing disease, see Clare M. Hasler, *Functional foods: Their role in disease prevention and health promotion*, 52 FOOD TECHNOL. 63-70 (1998).

[5] *See* DSHEA, *supra note* 4, § 2(15)(B).

[6] Provisions of the DSHEA permit manufacturers to market supplements with claims affirming the product's usefulness in maintaining good bodily function and structure, and under specific conditions, to claim that a supplement may be useful in preventing, mitigating and even treating certain diseases. *See*

Such sweeping regulatory and legislative reforms have been the subject of several congressional hearings, landmark lawsuits and exemplary grassroots activism. David Seckman, Chief Executive Officer of the Nutritional Foods Association estimates that the latter, "generated more mail and phone calls to legislators than any other topic since the Viet Nam War."[7]

The controversy stems from the gravity of regulatory changes. Prior to the 1990's, dietary supplements were regulated by the FDA as foods. As foods they could not be marketed with claims referring to diseases, unless they were sold as drugs.[8] Legislative changes creating exceptions to this principle were brought about in the 1990's. These changes occurred in the wake of a growing body of scientific evidence demonstrating the usefulness of certain dietary supplements in preventing certain illnesses and maintaining good health.[9] Thus, legislative changes authorizing efficacy claims were made because legislators were concerned that under the prevailing regime where dietary supplements were considered as foods, consumers were likely to underuse them because they could not receive (via label statements) information about their potential usefulness in preventing disease and maintaining good health.[10]

In 1994, the Clinton Administration responded to this concern – in economic terms, a loss of consumer welfare — by enacting the Dietary Supplement Health Education Act (DSHEA).[11] The DSHEA authorizes supplement manufacturers to make truthful label claims about the ability of a supplement to maintain good health and reduce the risk of certain diseases. In the same vein, the FDA Modernization Act (FDAMA)[12] that followed, expanded opportunities for supplement manufacturers to claim that such products could be useful in treating, mitigating and reducing the risk of certain diseases.

supra note 4. *See also e.g.*, 21 C.F.R. § 101.83 (explaining health claims allowed for the relationship between diets that include plant sterol/stanol esters and the risk of coronary heart disease (CHD)).

[7] NOW Foods, *Leaders in Dietary Supplement Industry Join Together to Form the Coalition to Preserve DSHEA* (May 5, 2004) (visited June 2, 2006) <http://www.nowfoods.com/index.php/Home/05.21.04--Leaders-in-Dietary-Supplement-Industry-Join-Together-to-Form-the-Coalition-to-Preserve-DSHEA/action/itemdetail/item_id/35967>.

[8] Regulatory code gives the FDA primary authority for the pre-market review of drugs, biologics and medical devices. *See* 21 C.F.R. § 3.4 (effective Nov. 23, 2005). Dietary supplements, being excluded from this category, were not subject to pre-market authorization. As foods, however, they could not be marketed with therapeutic claims.

[9] The origins of this movement can be traced to the impetus for the Nutritional Labeling Education Act (NLEA), which is best known for "Nutrition Facts" labeling, which the government introduced in order to reduce the incidence of diseases like CHD by helping consumers choose healthier foods. In addition to nutrient content claims, the NLEA also enabled manufacturers to make health claims describing the relationship between consumption of a food and disease. Because dietary supplements were regulated as foods, supplement manufacturers also applied for authorization of NLEA health claims for dietary supplements. *See* Bruce Silverglade, *Using Food Labeling to Improve Diet and Health: An Examination of the U.S. Nutrition Labeling and Education Act*, Center for Science in the Public Interest (visited July 6, 2005) <http://www.cspinet.org/reports/codex/labeling.htm>.

[10] *See* DSHEA *supra* note 4.

[11] Pub. L. No. 103-417, 108 Stat. 4325 (codified at 21 U.S.C. § 301 (1994)).

[12] Food and Drug Administration Modernization Act of 1997, Pub. L. 105-115.

An important consequence of these changes was that the FDA no longer held the exclusive right to determine whether a product could be regarded as efficacious in treating or preventing a disease. In the case of drugs, products approved for sale, are issued a New Drug Approval authorizing acceptable statements describing the efficacy of drugs in treating diseases. Language and statements not approved, but which may be in fact true, are suppressed. In the case of dietary supplements, this exclusivity principle was called into question and defeated in the courts.

For dietary supplements therefore, certain statements not evaluated by the FDA may appear on product labels if they are accompanied by an appropriate disclaimer or qualifying language. As such, dietary supplements now marketed with certain health claims now a disclaimer indicating that efficacy statements on the label "not been evaluated by the FDA, and that the product is not intended to diagnose, treat, prevent or mitigate any disease."[13]

Opponents of such regulation have argued that the disclaimer policy strips the FDA of the authority it needs to adequately protect consumers from dupery and unsafe products. [14] A further argument is that such disclaimers and other counterfactual statements do nothing more than confuse consumers. Proponents, on the other hand, argue that authorizing truthful statements improves social welfare by providing consumers with more accurate information.[15] Thus, according to this view, labelling regulations should be bound by principles of commercial free speech, as opposed to the exclusive review by FDA regulators.

Even though these views are often portrayed as being incompatible with each other, they can be reconciled, if one considers that each may be applied under different circumstances. On the one hand, increased government control (which enables certain efficacy statements to be suppressed) may be desirable under circumstances where there is a risk that a serious disease may go untreated. On the other hand, limitations on the FDA's exclusivity principle (i.e., fewer restrictions to commercial free speech) may be desirable where greater information (even if it involves uncertainty) may induce consumers to reap the benefits of improved dietary choices. Regulator preferences for control over labelling statements and consumer preferences for commercial free speech

[13] 21 C.F.R. § 101.93(c)(1).

[14] *See* Bruce H. Schindler, *Where's There's Smoke, There's Fire: The Dangers of the Unregulated Dietary Supplement Industry*, 42 N.Y.L. SCH. L. REV. 261, 275-77 (1998) (arguing that the DSHEA does not protect consumers from a variety of unsafe products including L-tryptophan and ephedrine).

[15] *See*, John W. Emord, *Pearson v. Shalala: The Beginning of the End for FDA Speech Suppression*, 19 J. OF PUB. POL'Y & MARKETING 139, 140 (2000) (arguing that providing consumers with more information, through, for example, product labels will "render consumers more impervious to the wiles of hucksters who have operated then and now outside the law"). Such views were held well before issues with the dietary supplement were raised. In the case of OTC drugs for example, the FDA was initially reluctant to approve claims and leaflet information that did not match its monographs, but which were nonetheless truthful. *See for example*, Stephen H. McNamara, *FDA Regulation of Labeling and the Developing Law of Commercial Free Speech* 37 FOOD DRUG COSM. L.J. 394, 399-401 (1982) (discussing the FDA's exclusivity policy as an example of how it unduly restricts the flow of truthful information to consumers by preventing manufacturers from using synonyms to approved monograph language).

should therefore be understood as integral components of a social welfare function. Viewed in this sense, desirable regulatory policy will strive to efficiently manage the attribution of manufacturer commercial free speech rights and consumer free choice rights.

As a regulatory instrument, the desirability of a disclaimer remains, however, an elusive concept. Most analyses by legal scholars and other commentators acknowledge the pros and cons or costs and benefits of specific legislation such as the DSHEA (which includes specific provisions for the use of disclaimers), but few, if any, systematically explain why a more permissive regime of labelling regulation that includes the use of disclaimers, may be preferred to agency exclusivity, or other regulatory instruments.

In this Article, I introduce a model of economic welfare based on two constructs of social welfare: consumer free choice (i.e., unrestricted access to products for self-medication) and commercial free speech (i.e., the consumer's right to receive information on the efficacy or usefulness of a product). Using this approach, I illustrate why, under limited circumstances, stronger statements of efficacy when combined with certain disclaimers, can serve collective consumer and regulator interests well. I argue that a disclaimer policy accomplishes this by facilitating a free flow of information.

For consumers, this means being able to receive information via certain statements of efficacy that, alone, would have been suppressed, but with a disclaimer causes a consumer to more carefully weigh the costs and benefits of using the product. For regulators, a disclaimer can induce an added measure of vigilance by consumers, while enabling them to enjoy the benefits of such potentially useful products.

Stated alternatively, disclaimers enable consumers to favourably leverage some of the rewards from interpreting incomplete information, while at the same time providing regulators with some degree of control over the conditions under which supplements are sold. In economic terms, disclaimers exploit the consumer's and regulator's differential preferences for free speech and free choice by allowing consumer's to give up free choice where they value it less, in exchange for greater information received from manufacturers under a regime of liberalized commercial free speech.

The economic model proposed herein attempts to illustrate that detractors of the disclaimer policy have not adequately appreciated that, under certain circumstances, restricting the rights (e.g., rights to an environment of commercial free speech) of one party so as to expand the rights of another can be a welfare-improving policy if the losses of one party offset the gains of the other. I show that a disclaimer functions in just such a manner, particularly when a strong statement of efficacy is matched with a strong disclaimer, a situation which might otherwise be understood as simply exacerbating consumer confusion. I discuss these tradeoffs in the context of three regulatory scenarios depending on whether supplements are marketed with drug claims, with so-called "structure/function" claims (purporting to maintain good health) and "health claims" (purporting to mitigate or treat disease).

I apply the model developed herein to draw normative and positive conclusions about the efficiency (hence desirability) of US dietary supplement regulatory policy. The normative claim is that, disclaimers should be used in the regulation of dietary supplement supplements because are a means of serving consumer and regulator's respective interests. They can provide greater direction to consumers in interpreting the relevance of stronger health claims.

The positive claim is that much of the recently codified FDA rules work towards this end. To be sure, several dispositions of the FDA's regulatory code suggest that the FDA has evolved from a gatekeeper of new technology to an information agent. At the time of writing, the FDA has yet to issue a final rule with regards to the use of disclaimers and qualifying statements in health claims. This Article suggests that a policy authorizing qualified health claims and disclaimers is likely to do more benefit than harm for consumers, while at the same time enabling the FDA to meet its goals of protecting the consumer.

In what follows, I provide background on the regulation of dietary supplements in Section II. Section III introduces, using graphical analysis, a model of economic welfare for dietary supplement regulations, while Section IV applies the core insights of this model to specific cases of supplement regulation. Conclusions appear in the final section.

II. BACKGROUND: REGULATION OF DIETARY SUPPLEMENTS

Although dietary supplement legislation addresses both safety and efficacy concerns, it is the efficacy claims for dietary supplements that remain most controversial. Such regulation for label statements has been developed through a litigious process, in which manufacturers invoked commercial free speech rights, and regulators, the need to protect consumers from what they viewed as potentially misleading claims. This section begins by describing the origins of the controversy over label claims and then provides an overview of the legislation itself. It concludes by explaining how the judicial interpretation of the Dietary Supplement Health Education Act was informed by commercial free speech doctrine, thereby creating three possible types of label claims for dietary supplements.

A. The Impetus for Changes to Dietary Supplement Regulation: An Improved Appreciation of the Consequences of Incomplete Information.

Through the Federal Food, Drug and Cosmetics Act (FDCA),[16] the main intent of dietary supplement regulation is to reduce the likelihood that an unsafe[17] or inefficacious product

[16] Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended 21 U.S.C. § 301 et seq.).

[17] Contrary to the popular belief that dietary supplements are "unregulated" in the USA, the FDA has a long tradition of statutory authority to regulate safety of dietary supplements. The DSHEA did not, moreover, alter the basic safety provision in the FDCA that since, 1906 has prohibited poisonous or harmful

will be used by an unsuspecting consumer. However, an often-ignored, yet equally important consideration which has been very influential in shaping food and drug regulation during the past two decades, is that denying approval for a supplement can deprive the consumer of what could be a means of treating, or preventing disease.[18] Failure to grant approval for a safe and effective product can create important welfare losses in the form of increased treatment costs for a more serious disease or reduced quality of life. Such losses may be particularly significant if, as in the case of coronary heart disease, a large number of individuals are afflicted and the disease is fatal or sincapacitating. Over the past two decades, with the rising costs of degenerative and chronic diseases,[19] governments turned to taking a more active role in promoting prevention and wellness.[20] An improved understanding about the role diet plays in preventing disease and maintaining good health also created an impetus for motivating consumers to increase their consumption of beneficial foods and supplements.

However, in the USA, an important legislative impediment to this reorientation towards wellness and prevention was that dietary supplements were initially classified as foods, and as such could not be marketed with claims making reference to disease prevention or treatment. Prior to the Nutrition Labeling and Education Act (NLEA)[21] and the Dietary Supplement Health Education Act (DSHEA),[22] only drugs and not foods could be marketed with claims that purported any substance-disease relationship.[23] Food

substances in foods. For an in-depth discussion of the FDA's authority in regulating the safety of dietary supplements, *see generally*, Peter B. Hutt. *FDA Statutory Authority to Regulate the Safety of Dietary Supplements*. 31 AM. J. OF LAW & MEDICINE, 155, 155-174 (2005) (reviewing all statutes and regulations used by the FDA to regulate the safety of dietary supplements).

[18] Indeed, during the 1980's, reducing FDA approval times for new drugs were an important government priority in the wake of diseases like AIDS and other diseases for which patients often had no other treatment options. *See* Stephen J. Ceccoli, *Policy Punctuations and Regulatory Drug Review*, 15 J. OF POL'Y HIST. 157 (2003) (describing changes in the drug regulatory process, such as "Fast Track" approval that reduced the time required to have new drugs approved).

[19] The National Center for Chronic Disease Prevention and Health Promotion of the CDC estimates that 90 million Americans suffer from chronic disease, which account for 75% of the nation's $1.4 trillion medical care costs. In 2001 alone, the $300 billion was spent on cardiovascular disease alone, and over $129 billion was attributed to lost productivity from this single disease. As the proportion of those over the age of 65 will double over the next 30 years, these costs are expected to increase exponentially: DEPARTMENT OF HEALTH AND HUMAN SERVICES, CENTERS FOR DISEASE CONTROL AND PREVENTION, CHRONIC DISEASE OVERVIEW, Nov. 18, 2005 (visited July 8, 2005) <http://www.cdc.gov/nccdphp/overview.htm>.

[20] In particular, as part of its mandate, the Center for Food Safety and Nutrition (CFSAN) of the FDA promotes good health and prevention of disease by overseeing the application of Nutrition Facts labeling regulation, which specifies recommended daily allowances for certain vitamins and minerals. The Office of Dietary Supplements of the National Institutes of Health, created in 1994, also coordinates and sponsors (through the NIH) scientific research on dietary supplements in addition to being a principal advisor to the Director of the National Institutes of Health, Centers for Disease Control and Prevention, and the Food and Drug Administration.

[21] Pub. L. 101-535, 21 U.S.C. § 343 (1994) [hereinafter *NLEA*].

[22] *See supra* note 4.

[23] 21 U.S.C. § 321 (f), defines food as: (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article. In 21 U.S.C. § 321(g)(1), a drug is defined as (A) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body

manufacturers occasionally suggested that certain foods rich in certain substances (e.g., "a diet rich in fibre may help reduce the likelihood of colon cancers")[24] could have an effect on reducing the likelihood of disease, but this was very much an *ad hoc* procedure, since it was not known whether the FDA would sanction such label claims.

From the standpoint of approval of such health claims, two types of errors can be committed when a wrong approval decision is taken. They are, in the language of statistical inference, "type 1" and "type 2" errors. A type 1 error is committed when approval is granted for an undesirable (i.e., unsafe and ineffective) product. A type 2 error, in contrast, is committed when approval is denied for a desirable (i.e., safe and effective) product, thereby causing consumers to incur a welfare loss in the form of worse health or more costly treatment.[25] In this regard, less restrictive labelling regulations can reduce type 2 errors by enabling manufacturers to make claims of efficacy that are likely to increase the use of beneficial supplements. However, because such a policy makes it easier to obtain approval, it also increases the likelihood that inefficacious products are used. In terms of type 1 and type 2 errors, attempting to minimize type 1 errors increases the likelihood of type 2 errors.

Two conditions can, however, reduce this inherent trade off between type 1 and type 2 errors. First, an approval based on an examination of a more complete and representative body of information which includes, for example, randomized clinical trials, could be

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of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) or sections 343(r)(1)(B) and 343(r)(5)(D), is made in accordance with the requirements of section 343(r) is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) is not a drug under clause (C) solely because the label or the labeling contains such a statement. Although FDA legislation now recognizes that certain foods can be beneficial in preventing certain diseases, foods were initially defined as being intended to curb hunger.

[24] Kellog's cereal marketing claim was one of the first to suggest that consumption of fibre could be beneficial in preventing a disease. In 1984, Kellog's opened the floodgates of health claims by including a claim on boxes of All-Bran stating that the cereal was high in fiber and that the National Cancer Institue had established that a high fiber diet could reduce the risk of some types of cancer. Kellog's did not consult with the FDA before attaching the claims to its cereal boxes, yet the Agency took no action against Kellog's. Other manufacturers interpreted the lack of FDA action as an invitation to flood the market with health-related claims; S*ee* Nicole Endejann, *Is the FDA's Nose Growing? : The FDA Does Not "Exaggerate*[ ] *Its Overall Place in the Universe*" *When Regulating Speech Incident to "Off –Label" Prescription Drug Labeling and Advertising*, 35 AKRON L. REV. 491, 514-516 (2001-2002).

[25] Whether an approval error is a type 1 or type 2 error depends on how the null hypothesis is defined, and is a frequent source of confusion when applied to the case of drug approval. If the null hypothesis is defined as "the product *is* safe and effective" then a type 1 error is committed when approval is *rejected*. A type 2 error is committed when approval is *granted* for a product that is not safe and effective. A number of commentators (Grabowski, 1983) define type 1 and type 2 errors in this manner. If we define the null hypothesis as "the product is *not* safe and effective" then a type 1 and type 2 error have the opposite meaning. A *type 1* error is committed when an undesirable product is *approved* and a *type 2* error is committed when approval is *denied* for a desirable product. In this paper, I use the latter conceptualisations of type 1 and type 2 errors because its definition of the null hypothesis corresponds more closely to the realities of approval procedure: in the absence of knowledge about the product, it is initially presumed unsafe and ineffective because the burden of proof lies with the sponsor. This conceptualisation of type 1 and type 2 errors is moreover consistent with most other uses of the term in the context of drug regulation.

helpful in supporting a claim of efficacy that would otherwise not be approved,[26] while at the same time reducing the likelihood of a type 1 error. Second, an improved understanding of the significance of clinical data may also enable regulators to grant approval where it may otherwise not have been possible. In 1987, for example, the American Medical Association (AMA) maintained that dietary supplements were unnecessary for individuals eating a varied diet, and should only be used for therapeutic purposes on the advice of a physician.[27] In 2002, however, the AMA radically changed its position, as a result of a consensus within the medical profession acknowledging the important role of vitamins and minerals in preventing disease and maintaining good health, and their favourable risk-benefit profile.[28] A new appreciation of the role of supplements militates in favor of allowing claims that suggest how a supplement may be helpful in preventing disease, and against suppression of such claims that are supported by emerging science but not necessarily proven by randomized clinical trials.

Changes in dietary supplement regulation have, therefore, allowed manufacturers to print claims of efficacy on product labels. Some of these claims associate substances found in supplements and foods with health maintenance and generally do not require pre-market authorization. However, certain claims purporting to cure or treat disease do require prior approval, and it is for these cases that the FDA may decline approval or request that the wording of a statement be changed. As I explain below, these changes, which were intended to restore a balance between type 1 and type 2 errors, occurred through a protracted process of amending the FDCA and FDA code, several facets of which were hotly contested in courts.

B. Dietary Supplement Legislation and Regulation

The NLEA of 1990 and the DSHEA of 1994[29] are the two legislative amendments that allow dietary manufacturers to claim that a supplement may be useful in treating,

[26] Several jurisdictions have begun to put in place regulatory procedures for the design of clinical trials for dietary supplements. Health Canada's Natural Health Products Directorate has recently developed guidelines for conducting clinical trials used to substantiate claims of efficacy. *See*, HEALTH CANADA, NATURAL HEALTH PRODUCTS DIRECTORATE, CLINICAL TRIALS FOR NATURAL HEALTH PRODUCTS, (October 2005) (visited Aug. 20, 2006) <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodnatur/clini_trials-essais_ nhp-psn_e.pdf>.

[27] American Medical Association, Council of Scientific Affairs, *Vitamin Preparation as Dietary Supplements and as Therapeutic Agents*, 257 JAMA 1929, 1931 (1987).

[28] *See* Kathleeen M. Fairfield & Robert H. Fletcher, *Vitamins for Chronic Disease Prevention in Adults*, 287 JAMA 3116, 3124 (2002) (indicating that "suboptimal" levels of vitamin consumption is associated with many chronic disease including cardiovascular disease, cancer and osteoporosis and that it is important for physicians to identify patients for increased vitamin needs). *See also* Robert H. Fletcher and Kathleen M. Fairfield, *Vitamins for Chronic Disease Prevention in Adults: Clinical Applications*, 287 JAMA 3127, 3127 (2002) (indicating that "Physicians should make specific efforts to learn about their patients' use of vitamins to ensure that they are taking vitamins … such as folate supplementation for women in the childbearing years …").

[29] See DSHEA, *supra* note 4.

preventing, or mitigating a disease.[30] For the purposes of enforcement, a disease is defined in Federal Code as:

> [D]amage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension); except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition.[31]

With this definition of disease, NLEA and DSHEA authorize respectively, the following types of claims: qualified health claims and structure/function claims.[32] In addition, a dietary supplement may be regulated as a drug, provided it meets all of the approval criteria, and was not available for sale as a food product prior to approval.

1. Nutrition Labeling Education Act

The 1990 NLEA authorized the FDA to approve health claims for foods and dietary supplements. Health claims define the relationship between a food or supplement ingredient and reducing the risk of a disease or health-related condition.[33] Early

[30] The following selective review of the NLEA and the DSHEA is not intended to represent the comprehensive efforts of Congress and the FDA to regulate dietary supplements. Rather it is intended to present an outline of what the author views as the principal laws that give rise to the issue of economic efficiency of health claims. For a more extensive review of the historical development of dietary supplement legislation see Laura A.W. Khatcheressian, *Regulation of Dietary Supplements: Five Years of DSHEA*, 54 FOOD & DRUG L.J. 623 (1999). *See also*, Arnold I. Friede, *Dietary Supplements: Background for Dialogue Between the Industry and the Medical Profession*, 53 FOOD & DRUG L.J. 413, 415-417 (1998).

[31] 21 C.F.R. §101.93(g)(1) (2005).

[32] In addition to health claims and structure/function claims, a supplement could be marketed with drug claims if controlled clinical trials are undertaken by the sponsor. However, this is rarely done in practice, because if a supplement was available as a food prior to its approval with drug claims, it will continue to be available as a food. Cranberry juice, for example, is widely recognized as being an effective treatment for urinary tract infections, but is not sold with drug claims because it was available as a food prior to its efficacy in treating such diseases was demonstrated. *See also infra* note 33.

[33] 21 U.S.C. §343(r)(1)(B) (2006). Health claims describe a relationship between a food, food component or dietary supplement ingredient, and reducing risk of a disease or health-related condition. There are three ways by which FDA exercises its oversight in determining which health claims may be used on a label or in labeling for a food or dietary supplement: 1) the 1990 Nutrition Labeling and Education Act (NLEA) provides for FDA to issue regulations authorizing health claims for foods and dietary supplements after FDA's careful review of the scientific evidence submitted in health claim petitions; 2) the 1997 Food and Drug Administration Modernization Act (FDAMA) provides for health claims based on an authoritative statement of a scientific body of the U.S. government or the National Academy of Sciences; such claims may be used after submission of a health claim notification to FDA; and 3) the 2003 FDA *Consumer Health Information for Better Nutrition Initiative* provides for qualified health claims where the quality and strength of the scientific evidence falls below that required for FDA to issue an authorizing regulation. Such health claims must be qualified to assure accuracy and non-misleading presentation to consumers. Structure/function claims have historically appeared on the labels of conventional foods and dietary supplements as well as drugs. However, the Dietary Supplement Health and Education Act of 1994 (DSHEA) established some special regulatory procedures for such claims for dietary supplement labels. Structure/function claims describe the role of a nutrient or dietary ingredient intended to affect normal structure or function in humans, for example, "calcium builds strong bones." In addition, they may

examples include statements of the relationship between soy and heart disease,[34] and folate and neural tube defects.[35] Although NLEA-approved health claims do require pre-market authorization, a significant difference with the case of drug claims is that they do not require the manufacturer to submit clinical trial data substantiating the claim. The NLEA authorized the FDA to create regulations that would allow such claims to be approved based on the FDA's examination of available scientific information. In particular, the NLEA required that the FDA review applications and authorize health claims according to a standard of Significant Scientific Agreement (SSA). This standard requires that the authorizing decision reflect the "the totality of publicly available scientific evidence [supporting the belief] that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims..."[36]

As a means of contending with the uncertainty or inconclusiveness of certain scientific studies, the NLEA authorized claims for food which included qualifying language in the form of words such as "may help" reduce the risk of certain disease. However, such qualifying language was rarely applied to supplements since the law created confusion as to whether it was intended to apply exclusively to foods or to dietary supplements (a category of products which was in itself not clearly defined). The significance of the NLEA is that it required the FDA to develop a framework for evaluating health claims, which, unlike drug claims, did not require the sponsor to conduct clinical trials. The FDA's response was to err on the side of "better safe than sorry" and consequently rarely approved any health claim for a supplement. In response to this regulatory hurdle, the supplement industry successfully lobbied Congress to impose a moratorium on the application of the NLEA, until a law specifically targeting dietary supplements could be

characterize the means by which a nutrient or dietary ingredient acts to maintain such structure or function, for example, "fiber maintains bowel regularity," or "antioxidants maintain cell integrity," or they may describe general well-being from consumption of a nutrient or dietary ingredient. Structure/function claims may also describe a benefit related to a nutrient deficiency disease (like vitamin C and scurvy), as long as the statement also tells how widespread such a disease is in the United States. The manufacturer is responsible for ensuring the accuracy and truthfulness of these claims; they are not pre-approved by FDA but must be truthful and not misleading. If a dietary supplement label includes such a claim, it must state in a "disclaimer" that FDA has not evaluated the claim**.** *See infra* note 44. *See also* U.S. FOOD AND DRUG ADMINISTRATION, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, CLAIMS THAT CAN BE MADE FOR CONVENTIONAL FOODS AND DIETARY SUPPLEMENTS, September 2003 [hereinafter *Claims*] (visited May 4, 2006) <http://www.cfsan.fda.gov/~dms/hclaims.html.>

[34] 21 C.F.R. § 101.82. An example of a model health claim for soy protein is "25 grams of soy protein a day, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of food] supplies __ grams of soy protein." *See* U.S. FOOD AND DRUG ADMINISTRATION, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, A FOOD LABELING GUIDE – APPENDIX C, (2004) [hereinafter *Labeling Guide*] (visited May 4, 2006) < http://www.cfsan.fda.gov/~dms/flg-6c.html>.

[35] 21 C.F.R. 101.79. *See also Labeling Guide*, *supra* note 34.

[36]Food, Drug and Cosmetic Act, 21 U.S.C. § 343(r)(3)(B)(i) (2006)). The FDA also issued a guidance document describing its interpretation of this statue as well as regulations, codified at 21 C.F.R. § 101.14(c). *See* U.S. FOOD AND DRUG ADMINISTRATION, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, GUIDANCE FOR INDUSTRY: SIGNIFICANT SCIENTIFIC AGREEMENT IN THE REVIEW OF HEALTH CLAIMS FOR CONVENTIONAL FOODS AND DIETARY SUPPLEMENTS, December 22, 1999 (visited May 5, 2006) <http://vm.cfsan.fda.gov/~dms/SSAguide.html>. As it turned out, the SSA standard was itself found to be problematic, and regarded by courts as being a violation of principles of administrative law.

enacted.[37] The DSHEA followed in 1994, clearly distinguishing supplements from foods and introducing a new category of label claims.

2. Dietary Supplement Health Education Act

The 1994 Dietary Supplement Health Education Act enacted by the Clinton Administration defined a supplement as any non-tobacco product not consumed for caloric intake (i.e., reducing hunger) that includes a vitamin, mineral, herb or other biological and amino acid.[38] These categories of products were thus distinguished from food in that they were consumed for their purported health benefits, advertised on product labels or other promotional material. The DSHEA amended the FDCA to include a second type of claim for dietary supplements: structure/function claims. Such claims characterize the role of a nutrient or dietary supplement in affecting (e.g., maintaining) normal body structures or functions in humans.[39] So-called "structure/function" claims may even establish the relationship between a disease and a nutrient provided the disease can be attributed to a nutrient deficiency (like vitamin C, to treat scurvy).[40] In contrast to the NLEA, the DSHEA authorizes such claims without pre-market authorization, provided two conditions are met.

First, prior to using the claim, the manufacturer must have substantiation (e.g., peer-reviewed scientific studies) that the claim is truthful and not misleading.[41] While the initial and more restrictive NLEA required the FDA to apply a standard of "significant scientific agreement"[42] to evidence submitted by applicants (in which the "totality of evidence available" supported the claim), the DSHEA shifts the burden of proof away from the manufacturer, requiring instead that the FDA demonstrate that a product is unsafe. Once the FDA meets its burden, a product may consequently be removed from the market or the FDA may take the liberty to deny the approval of a health claim request. The DSHEA is therefore a clear acknowledgement that as long as the product poses a relatively low health risk to consumers, it should be made available in conjunction with authorized structure/function claims so that consumers may reap the potential benefits of non-misleading claims. Claims that may nonetheless be based on inconclusive evidence. A key point here is that the law aims to enable consumers to be exposed to the risks resulting from inconclusive scientific evidence on a substance's efficacy. It does so because it is believed that the consequences of attempting to eliminate these risks would be a welfare loss resulting in the form of increased type 2 errors.

A second requirement for authorizing structure/function claims is that a disclaimer stating that the product "is not intended to diagnose, treat, cure, or prevent any disease"[43] appear

[37] *See* Laura A.W. Khatcherressian, *supra* note 30 at 625-626. *See also*, Prescription Drug User Fee Act, Pub. L. No. 102-571, 106 Stat. 4491 (codified in various sections of 21 U.S.C. §§ 301 et seq.).
[38] 21 U.S.C. § 321 (ff)(1)(A)-(D) (2006).
[39] *See Claims supra* note 33.
[40] *Id.*
[41] 21 U.S.C. § 343(r)(6)(B) (2006).
[42] 21 U.S.C. § 343(r)(3)(B)(i) (2006).
[43] *See Claims supra* note 33.

on the product label in proximity to the structure/function claim. In the same vein, the FDA's 2003 Consumer Health Information for Better Nutrition initiative provides for qualified health claims (i.e., health claims that include disclaimers or other qualifying language that limits the scope of interpretation) where there is "emerging evidence for a relationship between … a dietary supplement and reduced risk of a disease or health-related condition."[44] In other words, where any such claims of efficacy are made, a disclaimer must be included to indicate that evidence supporting the claim is inconclusive.

The use of disclaimers and other qualifying language is perhaps the most controversial aspect of the DSHEA, because it provides for the FDA to authorize certain health claims (i.e., those that do not meet the SSA standard) on the condition that they include counterfactual statements, suggesting why the claim may not be true. It is the result of what is now widely recognized as the most important judicial decision regarding dietary supplement legislation, *Pearson v. Shalala*[45] in which the authority of the FDA in suppressing potentially misleading statements was called into question.

In *Pearson*, petitioners Sandy Pearson and Durk Shaw, two supplement promoters, were initially denied by the FDA the right to apply (with the appropriate disclaimer) four health claims[46] on their supplement labels, on the grounds that the evidence available did not meet the FDA's standard of significant scientific agreement, as mandated by the NLEA.

While the trial court ruled in favour of the FDA, the appeals court reversed on two grounds. First, rejecting the FDA's contention that the government is not obliged to use a disclaimer approach, the appeals court ruled that the FDA's denial of four health claims accompanied by a disclaimer constituted a violation of the petitioner's First Amendment right protecting commercial free speech.[47] Second, the court opined that the standard of significant scientific agreement (SSA) initially set forth in the NLEA as promulgated by the FDA's regulation, did not result in a standard, but rather a description of the process by which the FDA chose to examine such applications. More specifically, while the FDA maintained that the standard for SSA could be reached when experts in the field with scientific training could arrive at a consensus as to the validity of the claim, its "unarticulated standard" did not permit the regulated party to "perceive the principles which are guiding agency action."[48] Accordingly, SSA amounted to a form of prior

[44] *See* U.S. FOOD AND DRUG ADMINISTRATION, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, CONSUMER HEALTH INFORMATION FOR BETTER NUTRITION INITIATIVE, July 10, 2003 (task force final report) (visited March 16, 2006) <http://www.cfsan.fda.gov/~dms/nuttftoc.html>.
[45] Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999).
[46] The four claims for which approval was sought are: "Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancers" ; (2) "Consumption of dietary fiber may reduce the risk of colorectal cancer" ; (3) "Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease" (4) "The U.S. Public Health Service has estimated that fifty percent of neural tube defects may be averted annually if all women maintained an adequate intake of folate during childbearing years" *See* Pearson v. Shalala, 14 F.Supp.2d 10 (D.D.C. 1998) (D.C. district court denying plaintiffs motion)
[47] *See Pearson supra* note 45, at 655, 658.
[48] *See id.* at 660.

restraint, giving the FDA undue discretion to approve claims on an enforcement discretion (case-by-case) basis.

Pearson therefore struck down the FDA's contention that only claims that met its discretionary standard of "significant scientific agreement" could appear on product labels. It also ruled that truthful statements not necessarily approved by the FDA could appear on product labels, provided that they were accompanied by a disclaimer. In this regard, some have argued that *Pearson* effectively removes an important margin of discretion that could have been used to keep unsafe products off the market.[49] DSHEA, in fact, in no way prevents the FDA from removing unsafe products from the market, since existing provisions of the FDCA preserve the FDA's powers to do so, but it does shift the burden of proof to the regulator.[50]

It is this last point that most clearly summarizes the shift in regulatory logic underlying the introduction of the NLEA and DSHEA, which may be summarized as follows. Prior to the DSHEA, consumers had relatively little government guidance in choosing dietary supplements because they were considered food products having little or no therapeutic value.[51] Following DSHEA, supplement regulation more clearly embraced objectives of prevention and health maintenance through improved diet. This is in sharp contrast to the

[49] *See* David C.Vladek, *Devaluing Truth: Unverified Health Claims in the Aftermath of Pearson vs. Shalala*, 54 FOOD & DRUG L.J. 535, 536 (1999), stating that although the Supreme Court, on occasion, has approved the use of government-required disclaimers to guard against potentially confusing or deceptive speech, the Court has never directed a government agency to permit potentially deceptive speech so long as it is accompanied by a disclaimer. Nor do any of the precedents cited in *Pearson* support its ruling with respect to marketing claims about products that can, and too often, pose real health threats to consumers. The Court made several errors in applying the *Central Hudson* test to the regulated health claims. The legislature was not afforded any deference in its decision to regulated dietary supplements health claims. Usually the government is given some latitude when the regulation incidentally restricts truthful information: *See* Nicole Endejann *supra* note 24, at 514-516. Congress, the FDA, and the courts must look to the medical models of information dissemination to determine whether the FDA's method of health sifting is appropriate under the free-flow theory. Where science and commerce meet, the courts and the government (administrative and legislative) must establish a new concept of speech protection that is more thorough than the commercial speech standard in order to allow public access to the non commercial, scientific component of such speech: *see* Amber K. Spencer, *The FDA Knows Best…Or Does It? First Amendment Protection of Health Claims on Dietary Supplements: Pearson v. Shalala*, 15 BYU J. PUB. L. 87, 103 (2000-2001).

[50] *See* Dietary Supplement Labeling Exemptions, 21 U.S.C. § 343–2 : "(a) IN GENERAL.—A publication, including an article, a chapter in a book, or an official abstract of a peer-reviewed scientific publication that appears in an article and was prepared by the author or the editors of the publication, which is reprinted in its entirety, shall not be defined as labeling when used in connection with the sale of a dietary supplement to consumers when it — … (c) BURDEN OF PROOF — In any proceeding brought under subsection (a), the burden of proof shall be on the United States to establish that an article or other such matter is false or misleading."

[51] Prior to the passage of the Dietary Supplement Health and Education Act (DSHEA), the FDA had significantly more control over dietary supplements. At that time, the FDA categorized dietary supplements as either drugs or food additives, both of which required approval before marketing. The DSHEA altered this scheme by taking dietary supplements out of the food additives category. The DSHEA categorized dietary supplements as foods, a category over which the FDA has no power to require clearance prior to marketing : See Stephanie Kauflin, *Dietary Supplements : Is Availability Worth the Risks ? Proposed Alternatives to the Present DSHEA Scheme*, 33 SETON HALL L. REV. 411, 412 (2002).

regulatory logic of the post WWII period in which regulation strived to ensure that clinically-proven safe and effective drugs were used to treat disease, and that the consumption decisions for such products were made not by consumers but by physicians prescribing or recommending them. In sum, several regulatory initiatives such as NLEA, DSHEA and more recently the Food and Drug Modernization Act (FDMA) provide consumers with greater access to potentially useful products intended for self-medication, health maintenance, and prevention of certain diseases. However, as described in the next section, this shift in regulatory logic occurred through a litigious process in which supplement promoters were vindicated by arguing that the restrictive FDA regulatory policies violated their commercial free speech rights.

C. The Application of Commercial Free Speech Doctrine to Supplement Regulation: The Emergence of Disclaimers and Qualified Health Claims

In ruling that the FDA's policy of suppressing potentially misleading label statements was in part unwarranted, given that these statements could be countered with an appropriate disclaimer, the appeals court in Pearson reasoned that the promoter's commercial free speech rights had to be protected. However, the courts also recognized that the regulatory agency had an obligation to protect consumers from potentially misleading label claims. To reconcile these objectives, and to more evenly balance the consequences of type 1 and type 2 errors, the courts applied a doctrine of commercial free speech seen in other areas of regulation to dietary supplement label claims.

Commercial free speech is distinguished from "pure" (e.g., political) free speech (protected by the First Amendment to the Constitution) in that it is defined as "that which is intended to motivate a purchase of a product".[52] Its protection, under the First

[52]As defined by the Supreme Court, commercial speech is a speech that does no more than propose a commercial transaction. In Central Hudson & Electric v. Public Service Commission of New York, 447 U.S. 557, 562 (1980) [hereinafter *Central Hudson*], the First Amendment, as applied to the States through the Fourteenth Amendment, protects commercial speech -- namely, expression related solely to the economic interest of the speaker and the speaker's audience -- from unwarranted governmental regulation; the government does not have complete power to suppress or regulate commercial speech. Stevens and Brennan, JJ., were dissidents in part from that holding, at 579-580. Stevens, J., states that one of the two definitions the Court uses in addressing that issue is too broad and the other may be somewhat too narrow. The Court first describes commercial speech as ""expression related solely to the economic interests of the speaker and its audience." … [A]lthough it is not entirely clear whether this definition uses the subject matter of the speech or the motivation of the speaker as the limiting factor, it seems clear to that it encompasses speech that is entitled to the maximum protection afforded by the First Amendment. Neither a labor leader's exhortation to strike, nor an economist's dissertation on the money supply, should receive any lesser protection because the subject matter concerns only the economic interests of the audience. Nor should the economic motivation of a speaker qualify his constitutional protection; even Shakespeare may have been motivated by the prospect of pecuniary reward. Thus, the Court's first definition of commercial speech is unquestionably too broad. The Court's second definition refers to "'speech proposing a commercial transaction." … [A] salesman's solicitation, a broker's offer, and a manufacturer's publication of a price list or the terms of his standard warranty would unquestionably fit within this concept. Presumably, the definition is intended to encompass advertising that advises possible buyers of the availability of specific products at specific prices and describes the advantages of purchasing such

Amendment to the Constitution, was first decided in 1975 in *Bigelow v. Virginia*.[53] In *Bigelow*, where the State of Virginia sought to ban advertisements for abortion referral, the court ruled that commercial speech in itself is not "valueless in the marketplace of ideas"[54] and more importantly, that just because a commercial activity was connected with speech, it did not obviate the need for protection. Moreover, since the ads concerned abortion, courts reasoned suppression of such speech would have more consequences than simply reduced sales for a business – the public could be deprived of an important service.

The limitations regarding restrictions to commercial free speech doctrine were decided a year later in *Virginia State Board of Pharmacy v. Virginia Citizens Council Inc*.[55] Here, the court ruled in favour of allowing pharmacists to advertise the price of prescription drugs in order to facilitate the flow of commercial information. This was in spite of the State Board's defense that such restraints on commercial free speech were necessary in order to prevent pharmacists from being driven out of business by unrelenting competition.[56] However, while this ruling established that protecting the sellers from

items. Perhaps it also extends to other communications that do little more than make the name of a product or a service more familiar to the general public. Whatever the precise contours of the concept, and perhaps it is too early to enunciate an exact formulation, [Stevens, J., is] persuaded that it should not include the entire range of communication that is embraced within the term "promotional advertising."" Indeed, the definition does not offer proper protection to consumers, allowing speakers to label products with claims that do not inform the consumers. Commercial free speech in the context of regulating dietary supplements should address issues not pertaining solely to economic interests of the speaker. *See also* Virginia Pharmacy Board v. Virginia Citizens Consumer Council, 425 U.S. 748, 762 (1976); Bates v. State Bar of Arizona, 433 U.S. 350, 363-364 (1977); Friedman v. Rogers, 440 U.S. 1, 11 (1979).

[53] 421 U.S. 809, 822, 826 (1975)

[54] *See* Bigelow v. Virginia, 421 U.S. 809, 826 (1975) (stating that a State may not, under the guise of exercising internal police powers, bar a citizen of another State from disseminating information about an activity that is legal in that State). The Court wrote that " the Virginia courts erred in their assumptions that advertising, as such, was entitled to no First Amendment protection and that appellant Bigelow had no legitimate First Amendment interest … Advertising, like all public expression, may be subject to reasonable regulation that serves a legitimate public interest." *See* Pittsburgh Press Co. v. Pittsburgh Commission on Human Relations, 413 U.S. 376 (1973); Lehman v. City of Shaker Heights, 418 U.S. 298 (1974) (the Court also stated that "to the extent that commercial activity is subject to regulation, the relationship of speech to that activity may be one factor, among others, to be considered in weighing the governmental interest alleged. Advertising is not thereby stripped of all First Amendment protection.").

[55] *See* Virginia State Board of Pharmacy v. Virginia Citizens Council Inc., *supra* note 52.

[56] *Id.* at 765. Advertising, however tasteless and excessive it sometimes may seem, is nonetheless dissemination of information as to who is producing and selling what product, for what reason, and at what price. So long as we preserve a predominantly free enterprise economy, the allocation of our resources in large measure will be made through numerous private economic decisions. It is a matter of public interest that those decisions, in the aggregate, be intelligent and well informed. To this end, the free flow of commercial information is indispensable. *See* Dun & Bradstreet, Inc. v. Grove, 404 U.S. 898, 904-906 (1971) (Douglas, J., dissenting from denial of certiorari). See also F.T.C. v. Procter & Gamble Co., 386 U.S. 568, 603-604 (1967) (Harlan, J., concurring). And if it is indispensable to the proper allocation of resources in a free enterprise system, it is also indispensable to the formation of intelligent opinions as to

increased competition could not be used as a justification for suppressing commercial free speech, it was silent with respect to the broader question of when a regulatory agency should be allowed to suppress commercial free speech in the interest of public welfare.

Such a test was spelled out in *Central Hudson & Electric v. Public Service Commission of New York*.[57] In *Central Hudson*, the Public Service Commission sought to ban advertising by *Central Hudson* promoting the use of electricity, in order to prevent shortages. In ruling that such a ban was not permissible, the court established a four-part test to determine whether the restriction is permissible. In formulating this rule the *Central Hudson* court stated that,

> At the outset, we must determine whether the expression is protected by the First Amendment. For commercial speech to come within that provision, it at least must concern lawful activity and not be misleading. Next, we ask whether the asserted government interest is substantial. If both enquiries yield positive answers, we must determine whether the regulation directly advances the government interest asserted, and whether it is not more extensive than is necessary to serve that interest. [58]

how that system ought to be regulated or altered. Therefore, even if the First Amendment were thought to be primarily an instrument to enlighten public decision making in a democracy, we could not say that the free flow of information does not serve that goal. As for the State's contention, *see id*. at 768-770: Price advertising, it is argued, will place in jeopardy the pharmacist's expertise and, with it, the customer's health. It is claimed that the aggressive price competition that will result from unlimited advertising will make it impossible for the pharmacist to supply professional services in the compounding, handling, and dispensing of prescription drugs. Such services are time consuming and expensive; if competitors who economize by eliminating them are permitted to advertise their resulting lower prices, the more painstaking and conscientious pharmacist will be forced either to follow suit or to go out of business. It is also claimed that prices might not necessarily fall as a result of advertising. If one pharmacist advertises, others must, and the resulting expense will inflate the cost of drugs. It is further claimed that advertising will lead people to shop for their prescription drugs among the various pharmacists who offer the lowest prices, and the loss of stable pharmacist-customer relationships will make individual attention - and certainly the practice of monitoring - impossible. Finally, it is argued that damage will be done to the professional image of the pharmacist. This image, that of a skilled and specialized craftsman, attracts talent to the profession and reinforces the better habits of those who are in it. Price advertising, it is said, will reduce the pharmacist's status to that of a mere retailer. The Court rejected these contentions by arguing that the challenge now made, however, is based on the First Amendment. This casts the Board's justifications in a different light, for on close inspection it is seen that the State's protectiveness of its citizens rests in large measure on the advantages of their being kept in ignorance. The advertising ban does not directly affect professional standards one way or the other. It affects them only through the reactions it is assumed people will have to the free flow of drug price information. There is no claim that the advertising ban in any way prevents the cutting of corners by the pharmacist who is so inclined. That pharmacist is likely to cut corners in any event. The only effect the advertising ban has on him is to insulate him from price competition and to open the way for him to make a substantial, and perhaps even excessive, profit in addition to providing an inferior service. The more painstaking pharmacist is also protected but, again, it is a protection based in large part on public ignorance.

[57] *See Central Hudson supra* note 52.
[58] *Id.*at 566.

A preference for a least restrictive means of regulation criterion outlined in *Central Hudson*, was later reiterated in *Liquormart, Inc. v. Rhode Island*[59] and *In re R.M.J.*[60] As in *Central Hudson*, Rhode Island State laws banning ads with liquor prices were overturned in *Liquormart* because public interest in limiting alcohol consumption could be achieved in other ways which did not necessarily restrict free speech. In the same vein, in *R.M.J*. the Supreme Court reiterated the Central Hudson test, reversing the reprimand of a Missourri real estate agent for having used the word "real estate" in place of "property" – the latter being part of the limited terminology approved by the Missouri Supreme Court.

The appeals court in *Pearson* applied the Central Hudson test to determine whether the FDA should be able to suppress information that did not meet its SSA standard, but, as in *R.M.J*., was nevertheless truthful. In applying this test, the court understood that all scientific claims of efficacy involved some degree of uncertainty[61] and a certain degree of dissonance among a group of scientific experts did not necessarily mean that the claim was inherently misleading. Hence, it ruled that the FDA policy of preventing non-misleading statements not evaluated by the FDA failed to meet the final prong of the Central Hudson test, because it was not the least extensive way of protecting the public from misleading statements. More specifically, a less restrictive, but equally effective means of protecting the public is to apply disclaimers and counterfactual statements.[62] These include, for example, statements like: "These statements have not been evaluated by the FDA. This product is not intended to diagnose treat or cure any disease."

Following the *Pearson* opinion, First Amendment rights were seen by supplement promoters as a renewed opportunity for stronger structure/function claims to appear on product labels.[63] However, because such policies also enabled supplements to be treated as closer substitutes to drugs, the FDA set forth ten criteria for determining whether a claim qualifies as a structure/function claim (exempt from pre-market authorization) or a disease claim (requiring pre-market authorization because it is a health claim or a drug claim).[64] Such criteria are applied to determine whether the claims are intended to suggest that the product could be used as a drug (i.e., to treat, cure or mitigate a disease) by making reference to disease symptoms, names or other criteria. In applying such a policy, the FDA argues that its regulatory code requiring pre-market authorization for certain supplement claims[65] does not, as critics argue, violate commercial free speech rights, but merely defines the conditions under which a claim shall be treated as a structure/function or disease claim.[66]

[59] 517 U.S. 484 (1996).
[60] 455 U.S. 191 (U.S.Mo., 1982).
[61] *See* John Emord, *supra* note 15.
[62] *See* Pearson v. Shalala, *supra* note 45, at 659-660.
[63] *See* Nicole Endejann, *supra* note 24, at 503, 519.
[64] *See Claims supra* note 33.
[65] 21 C.F.R. 101.93(f).
[66] *See Claims supra* note 33.

The main consequence of *Pearson* has been to increase the specificity of government control. By developing a set of structure/function claims for supplements, regulators effectively increase their prescriptive control, by reducing the likelihood that products authorized with structure/function claims will be used to treat a disease. This is so, because the structure/function claim requires a disclaimer stating that the product has neither been approved for, nor is it intended for certain uses. In many respects, qualifying statements and disclaimers suggest to the consumer why a product should not be used for certain conditions.

In sum, the foregoing survey of the doctrine of commercial free speech as it applies to dietary supplement claims enables us to draw three conclusions. First, lessening commercial restrictions over free speech while maintaining some degree of government regulation of claims, is a desirable social ideal. Opinions spanning *Virgina Board* to *R.M.J.* advocate lessening restrictions to commercial free speech while, recognizing the necessity of protecting consumers from dupery. Second, courts recognize that disclaimers and qualified statements are a least restrictive means of preserving free speech rights. Third, increasing the specificity of regulations so as to increase the influence of the regulatory organization in motivating consumer choice, does not necessarily diminish consumer welfare, and particularly so, in cases where the consumer may not be qualified to make informed choices. In such instances, regulators should provide the consumer with more information in the form of disclaimers and qualifying statements indicate when a supplement should not be used. These concerns guided reforms to food and drug legislation that allows dietary supplements to be sold with qualified health claims, structure/function claims and even drug claims. In the next section, I propose how these ideas may be represented in an economic model of social welfare.

III. AN ECONOMIC MODEL OF THE WELFARE IMPACT OF DIETARY SUPPLEMENT REGULATION

As I have argued above, in situations where type 1 errors are of greater concern, a default rule that grants greater regulatory control to the regulatory agency is desirable. Conversely, in situations where type 2 errors are of greater concern, the doctrine espoused in *Pearson* is desirable, implying a lessening of restrictions to commercial free speech. Because consumer and regulator interests are sensitive to the context in which dietary supplements are being used, so too will the pareto efficiency of the regulatory system.

While the doctrine expressed in *Pearson* has emphasized the importance of minimizing restrictions to commercial free speech, it has not appreciated that reducing labeling restrictions through the concurrent use of disclaimers need not reduce the regulator's ability to protect the consumer. This is so because transferring rights (e.g., commercial free speech rights) from a party having a low marginal valuation (regulator) to another having a high marginal valuation (consumer) can create a net improvement in collective welfare.

Economists have defined efficiency criteria of social welfare with just such considerations in mind. More specifically, when two parties are able to trade, the preferences of each agent determine the extent to which resources are used efficiently to serve collective interests. Just as in the case of determining the optimal allocation of scarce goods between agents having different marginal valuations,[67] general equilibrium analysis can be used to make normative and positive claims about the efficiency of a regulatory policy. Applying this thinking, I treat the problem of regulating a new technology as an exchange of two goods between two individuals. The "goods" in question are rights to suppress commercial speech, and authority over the purchase of certain risky products, like dietary supplements. The "individuals" in question are, of course, the consumer and the regulatory agency. Conceptualising public policy in this manner demonstrates that collective welfare of regulator and consumer can be increased if parties are able to engage in mutually beneficial exchanges of these rights. In the sections that follow, I present the components of a basic model illustrating an efficient exchange of commercial free speech and consumer free choice rights.

A. Regulatory Instruments: Control Over Commercial Free Speech and Consumer Free Choice

1. Control Over Commercial Free Speech

As described in *Central Hudson*, for the government regulatory agency, exercising control over commercial free speech rights means having the authority to suppress certain product claims. Conversely, if the regulatory agency has relatively few rights to restrict freedom of speech, the consumer benefits from an environment of unrestricted commercial free speech in which product sponsors may make label claims that are intended to suggest that a product may be useful for a particular use. As described further below, the intended use depends on whether the product is marketed with a qualified health, structure/function claim or a drug (disease) claim. Thus, at issue is not the commercial free speech as such, but rather how commercial free speech will be manifested in the market, as a result of the extent to which the law grants powers to the consumer or the regulator. If considerable powers are granted to the consumer, it is assumed that these will be exercised by consumers demanding that regulatory restrictions to label statements be lifted, in order to facilitate the free flow of information from manufacturers to consumers. However, because consumers have different preferences for free speech and free choice depending on whether they intend to use the product cure or prevent disease, it will be efficient to authorize structure/function claims in some situations, while disclaimers and qualified health claims which provide regulators with some degree of influence over consumer choice, will be efficient in others.

[67] *See* WALTER NICHOLSON, MICROECONOMIC THEORY: BASIC PRINCIPLES AND EXTENSIONS 614 (3rd ed. 1984) (describing an efficient allocation of scarce goods as occurring when the marginal valuation for each good by each agent is the same). With trade, an agent having a relatively low marginal valuation for a scarce good (e.g., because she holds more of it than she really needs) may exchange it with another agent in the same situation. Such mutually beneficial trade is regarded as Pareto-improving, because it makes both agents relatively better off.

2. Control Over Consumer Free Choice

In addition to the rights to suppress commercial free speech, we may also define a second right as authority over consumption decisions. Authority refers to the extent to which a consumer may freely choose (e.g., via instrumental choice) to purchase a product. In the case where a consumer has complete authority over her consumption decision, a product may be purchased over the counter (i.e., without a prescription) and is not generally purchased on the advice of a physician. A consumer is assumed to make product choices based on rational (instrumental) analysis in which the costs and expected benefits are weighed. In some cases, a consumer has neither the information nor the expertise to make such informed choices and it is in these situations where a product may be purchased on the advice of an expert, or by prescription. Contrary to the case of instrumental choice, we can think of the latter as a case of "directed" choice, in which the state, or a regulatory agency restricts the availability of certain products like prescription drugs, thereby eliminating the consumer's free choice.

Middlegrounds to these two extremes, such as the case of so-called "ethical drugs" marketed to doctors (e.g., cough syrups, analgesics, vitamin supplements) and OTCs marketed directly to consumers.[68] Furthermore, whether the consumer's choice is portrayed as instrumental (rational) or directed[69] may also depend on the labelling requirements for directions on how and when a product should be used. Thus, where a dietary supplement requires a dosage directive, but is available without prescription, the consumer maintains considerable, but not a totality of authority over consumption decisions.

Consumers are assumed to prefer free choice in cases where there is no serious concern for type 1 errors, that is, there is no risk that instrumental (*i.e.*, the consumer's own) choice will result in a bad consumption decision. Regulators are assumed to prefer some degree of control over none, since it provides them with a means of preventing a product from being improvidently selected by the consumer. However, where type 2 errors are of greater concern, the FDA may wish to make greater allowances for commercial free speech, but require an increased level of prescriptive guidance (i.e., reduced levels of free choice) for consumers. Different scenarios thus create different assumptions about consumer and regulator preferences for free speech and free choice. To understand the impact of the distribution of commercial free speech and consumer free choice rights on collective (i.e., consumer and regulator) welfare, it is useful to illustrate these relationships graphically.

[68] For example, the Canadian Food and Drugs Act (R.S.C. 1985, c. F-27, s. 3) defines the medical conditions for which manufacturers may not make advertising claims. Those conditions not appearing on the so-called "Schedule A" are, however, conditions for which manufacturers are permitted to make advertising claims for products intended for OTC sale.

[69] *See* PETER TEMIN, TAKING YOUR MEDECINE: DRUG REGULATION IN THE UNITED STATES (1980) (making the distinction between "instrumental" and "hierarchical" choice). Instrumental choice refers to the consumer's rational decision process, while the hierarchical choice refers to government making such choices on behalf of consumers, by making certain products available by prescription only.

B. Edgeworth Box: A Graphical Representation of the Welfare Impact of Regulatory Policy

The central thesis of this paper -- that when parties have relatively low marginal valuations for rights of free speech and free choice, it will be efficient to trade them away -- is illustrated using a graphical representation well known to economists: an Edgeworth box. The Edgeworth box describes how the collective welfare of two parties within a two-good, closed economy may be improved through a mutual exchange of surplus goods for scarce goods.[70] This method of graphical analysis is applied to the case of commercial free speech and free choice rights defined above.

As shown in Figure 1, each party's welfare ("utility") is illustrated by her respective indifference curve (U), which represents a preference ordering set for various different allocations of free speech and free choice rights outlined above. Rights for commercial free speech appear on the Y axis, while rights for free choice (consumer's instrumental choice) appear on the X axis. A key point in this representation is that the allocation of rights is mutually exclusive. Thus, if consumers benefit from extensive commercial free speech rights, regulators necessarily have few opportunities to curtail commercial free speech,[71] as can be seen by the fact that axes are inverted (i.e., correspond to negative values in north and east directions) for the regulator.

Insert Figure 1 about here

For the consumer (agent C), since any point to the northeast of the initial indifference curve U_C will be strictly preferred, U'_C represents a higher level of welfare. The same is true for the regulator, whose indifference curves appear as concave curves,[72] as U_R and U'_R respectively, as a result of the x and y axes being inverted. Combining the indifference curves of both agents in a single diagram allows us to see how the welfare of each party changes under different allocations of rights to suppress commercial free speech and authority over consumption decisions.

The convex shape of each indifference curve indicates that convex combinations of each of the goods are strictly preferred to any allocation that provides one right to the exclusion of the other. For the consumer, this is a situation in which rights are analogous

[70] See NICHOLSON, *infra* note 65 at 612 (describing how an Edgeworth Box diagram portrays the respective endowments of two agents in a two-good economy. In such a diagram, "contract curve" describes the efficient allocations of these two goods between agents, in the sense that all points off this curve (i.e., where each agent's marginal valuation for a good is different) correspond to an allocation of goods that makes at least one agent worse off).

[71] The Y axis indicates, strictly speaking, which party has *control* over free speech. If the consumer has considerable control over such rights, then it is assumed (based on her preferences) that this will reduce restrictions on commercial free speech. The regulator being preoccupied with dupery, on the other hand, shall exercise any such right by limiting the persuasive statements that can be made by the seller. A few assumptions about the manufacturers, consumers and regulator preferences are therefore subsumed.

[72] As in the case of the consumer, the concave curves correspond to a convexity of preferences over rights to restricting commercial free speech and consumer free choice (i.e., exercising authority over the consumer's choice).

to two ordinary goods, in that because they are not perfectly substitutable, a combination of both is preferable to an unequal distribution of the two. Thus, for example, extremely unequal allocations (e.g. point A, where consumer has considerable authority over consumption decisions but relatively few rights to protect commercial free speech) the marginal rates of substitution between each right (i.e., the slope of the indifference curve) is relatively high for one right in relation to the other.

Comparing the initial allocation A with that of B, both consumer and regulator have incentives to bargain to an alternative allocation B, which provides both with a more equal distribution of both rights, since $U'_C > U_C$ and $U'_R > U_R$. Put differently, any point that lies in the lens-shaped region circumscribed by the two initial indifference curves U_C and U_R, is preferable to the initial allocation. Agents will therefore voluntarily resort to a trading institution that makes such exchanges possible, such as a market in which goods are exchanged according to prices that reflect the value of each good in relation to the other.

Applying this analogy to the case of commercial free speech and authority over consumption choices, a legal institution that makes such an exchange possible would be a welfare-improving one. Although stronger forms of efficiency address equity, that is, how the optimal allocation of goods (rights) should be established with regard to their initial allocation levels (i.e., given that the marginal value for "rich" will not be the same as for "poor") the forgoing graphical analysis abstracts from these considerations.

The Edgeworth representation thus subsumes three important conditions. First, rights to commercial free speech and consumer free choice[73] are limited and must be allocated between two parties. Second, where each party has declining marginal valuations for each right (owing to the convexity of preferences), having a mix of the two rights is always preferable to having one, to the exclusion of the other. Consumers prefer such a mix because it enables them to exercise some degree of free choice, while restrictions to commercial free speech help reduce confusion from a barrage of potentially misleading, unregulated advertisements. Finally, where rights are unequally distributed, parties will be willing to bargain to mutually beneficial allocation of such rights, by "trading them away" – accepting an alternative legal regime in which some rights are given up in order to increase rights to others. But while the efficiency of such arrangements may be immediately apparent in this example, it is in fact largely dependent on whether type 1 or type 2 errors are the main concern.

C. Consumer and Regulator Preferences Under Type 1 and Type 2 Errors

1. Type 1 errors

[73] Recall that the case where consumer free choice rights are held by the regulator corresponds to a situation in which the regulator has considerable control over the conditions in which the product is used. For example, the regulator may make certain products available by prescription only, and even limit the type of advertising that can be made for such products.

As mentioned in Part II a, type 1 and type 2 errors can result in very different health outcomes for the consumer. Accordingly, consumer preferences, (i.e., indifference curves) for commercial free speech and free choice will be defined by whether consumers are more concerned about type 1 or type 2 errors. Recall that when a regulatory type 1 error is committed, an inefficacious drug is approved for sale,[74] creating the potential that it may be used by the consumer in place of an effective treatment. Here, the main concern is that using an inefficacious dietary supplement prevents a patient from seeking immediate medical attention, thereby risking progression of a serious disease that may be more difficult or impossible to treat later on. Thus, where it is more desirable to avoid a potentially inefficacious course of treatment long term (e.g., by taking dietary supplements), the consumer will prefer suppression of label statements that have not been substantiated to the same degree as for a drug. The consumer will also prefer to be directed in the use of such products such as approved indications and directions for use. Put differently, where the consumer's major concern is type 1 error, commercial free speech and free choice (consumer instrumental choice) are "bads." In contrast to the consumer indifference curve in Figure 1, the indifference curve (U_C) in situations where type 1 errors are the principal concern and reason for selecting a product will be inverted, indicating that reduced levels of free speech and free choice rights are desirable. Regulator indifference curves, on the other hand, depict a high preference for control over commercial free speech and consumer free choice, as would be the case for a prescription drug. In this case, regulator and consumer preferences are likely to be aligned.

2. Type 2 errors

Concern for type 2 errors, in contrast, occurs where the consumer's primary objective is prevention or mitigation of a chronic, self-limiting or degenerative disease. Type 2 errors are also of concern for more serious diseases like cancer, where prevention is a goal and there is a larger window of opportunity to reap the benefits of the product, without substantially increasing the risk that the disease will be untreatable at a later date. Thus, even though the consumer may be more concerned about type 1 errors if she is afflicted with cancer, there is no inconsistency in preferences if she is nonetheless concerned with type 2 error (that potentially useful products remain inaccessible due to regulation) when attempting to reduce the likelihood of developing the same disease. This is so because the benefits of prevention (while the patient is healthy) are more desirable than treatment at a later date, and because taking the product does not reduce the likelihood that the disease will be detected later or not at all. Situations of type 2 error are therefore those in which the consumer would have regretted not using a product for which there was a reasonable presumption of efficacy in prevention or mitigation of a disease.

In Figure 1, it is shown that both consumer and regulator value control over commercial free speech rights and consumer free choice. Control over commercial free speech rights is valuable for the consumer because she will use it to demand a lessening of restrictions

[74] For the purposes of this discussion, we are solely concerned with such errors as they pertain to efficacy because the FDA may remove any product that is deemed to be unsafe at any time.

on statements that could inform her of the ability of a supplement to prevent a disease. Free choice is also valued by the consumer, because it enables her to use the product as she sees fit, and without having to obtain a prescription. Both rights are thus portrayed as "goods" with the consumer having convex preferences.

The regulator, however, also being concerned with dubious claims, also values the right to maintain some degree of restrictions on statements that could be made by sellers. Even in light of the necessity to reduce type 2 errors, the regulator is still concerned with type 1 errors because of the adverse consequences (loss of confidence in the regulatory agency, tarnished reputation) of a dubious claim or an undesirable product reaching the market. As the review of the implementation of the NLEA and the *Pearson* decision suggest, the FDA's inclination to minimize type 1 errors in the case of dietary supplements appears to be tied to institutionalized practices for drug approval. Pre-market review of health claims are intended to prevent dubious claims from being applied (a type 1 error), but there is no requirement that supplement manufacturers make qualified health claims that would reduce type 2 errors. In particular, prior to *Pearson v. Shalala*, and even after ratification of the DSHEA, the "default" position of the FDA was to suppress any claim that could not be substantiated by a preponderance of scientific evidence ("significant scientific agreement").[75] Thus, if no such studies were available, or if adequately controlled randomized clinical trials had not been conducted, the regulatory logic in place prevented consumers from realizing the benefits of reducing type 2 errors, in that they suppressed label claims that would otherwise induce consumers to consume the supplement.

One means of reducing type 2 errors, without reducing type 1 errors, is by requiring that statements bear disclaimers or qualifying language. Such statements can allow for stronger statements of efficacy (as a result of fewer restrictions to commercial free speech) without increasing type 1 errors, if the disclaimers explain why a statement may be misleading or of limited significance. In essence, a reduction in restrictions on consumer free speech need not increase type 1 errors if some consumer free choice rights are accorded to the regulator so as to enable the disclaimer to function in a prescriptive role. In this sense, the FDA's appreciation for reducing type 2 errors may be characterized in terms of a different set of indifference curves for the cases of structure/function or health claims, depending on the nature of counterfactual statements and qualified claims that are authorized for each of these classes of claims. The next section explains how these differences may be graphically represented, and the efficiency consequences of such regulations are analysed.

[75] In reviewing the FDA's record, Congress determined that the FDA has interpreted "significant scientific agreement" for health claims review (its undefined standard) in a "way that limits consumer access to important information on diet" and expressed its concern that the "FDA's treatment of health claims on dietary supplements and its implementation of the health claims standard is hindering, rather than fostering, the dissemination of truthful and non-misleading information about the nutrient/disease relationship". Congress faulted the FDA for requiring near-conclusive proof of a nutrient-disease association before authorizing health claims, explaining that despite the fact that the scientific literature increasingly reveals the potential health benefits of dietary supplements, The Food and Drug Administration has pursued a regulatory agenda that discourages their use by citizens seeking to improve their health through dietary supplementation. *See* John Emord *supra* note 15, at 139-140.

IV. ECONOMIC EFFICIENCY OF DIETARY SUPPLEMENT REGULATION

With the stakeholders defined as the consumer and the regulator, and recognizing that each may have different preferences for free speech and free (instrumental) consumer choice depending on whether a product is intended to cure a disease or prevent it, we can examine the question of whether current regulation is efficient. Efficiency is defined as the extent to which a regulation allows both consumer and regulator objectives (preferences) to be satisfied depending on whether supplements are marketed with drug, structure/function or qualified health claims.

The underlying assumption of this categorization of claims is that dietary supplements are used for different purposes. They may be consumed in order to reduce the risk of certain diseases like cancer or maintain good health. It's also worth reiterating that in each of the three cases, the product is assumed to be safe because of its generally recognized as safe (GRAS) status or because there has been sufficient toxicity data submitted to the FDA. The foregoing analysis is therefore limited to efficacy claims.

A. Drug Claims

A supplement may be approved by the FDA as a drug if it claims to treat a disease and such claims have been substantiated by controlled clinical trials,[76] and other evaluation criteria used by the FDA to evaluate drugs. Well controlled, randomized trials are intended to provide users with objective measures of efficacy that lessen the likelihood that an inefficacious product will be used to treat a disease (a type 1 error).

Dietary supplements marketed with drug claims are natural source drugs. The consumer expectations are that it shall be effective in treating disease and that the product is not to be consumed in the absence of disease. Such consumption patterns are consistent with an important concern for type 1 errors and little or no concern for type 2 errors. Strict controls over allowable efficacy claims and restrictions on the use of the drug are therefore desirable, not only from the consumer's perspective, but also from the regulator's.

Panel A of Figure 2 illustrates the case where consumer preferences are atypical (the utility curve has an "inverted" shape), and an ordinary indifference curve of a regulator, who values rights over the suppression of commercial free speech and consumer free choice. For the consumer, a more liberalized environment of commercial free speech and

[76] Robert G. Pinco & Todd H. Halpern, *Guidelines for the Promotion of Dietary Supplements: Examining Government Regulation Five Years After Enactment of the Dietary Supplement Health and Education Act of 1994*, 54 FOOD & DRUG L.J. 567, 571 (1999). A supplement may be treated as a drug if it claims to treat certain diseases. However, if it was first available as a food, then it does not need to be regulated as a drug. The reverse is more complicated but generally does not raise an issue of safety as much as it does product exclusivity.

instrumental choice are "bads". Preference sets towards the southwest (towards the consumer's origin), therefore corresponding to *higher* levels of satisfaction, since in this case the consumer prefers restrictions to commercial free speech as well as instrumental (free) choice, so as to prevent being misled by label statements and avoid using an inefficacious dietary supplement to treat a potentially serious disease. In the limit, a complete ban on commercial free speech and free choice (a point located in the bottom left hand corner of Panel A), maximizes the consumer's and the regulator's welfare.

Insert Figure 2 about here

With these considerations in mind, the current regulatory policy of restricting claims to those only approved by the FDA, thereby limiting the consumer's choice of products, by, for example, requiring that they be sold by prescription, is efficient. It provides both consumers and regulators with the protection they desire, that is, from committing type 1 errors. Disclaimers are not permitted in the case of drug claims, and the normative claim of this analysis is that they should not be, because there is no advantage to attempting to minimize type 2 errors at the expense of increasing type 1 errors.

In practice, there are relatively few opportunities for foods or supplements to be marketed as drugs. While a sponsor may apply to have a food or supplement marketed with drug claims, such approved claims cannot prevent it from being sold as a food or supplement (i.e., sold without prescription or without labels), if it were first available as a food, or any other substance that is GRAS.[77] The positive claim of this analysis is therefore that, while marketing certain dietary supplements with disease claims can be efficient, it may not be commercially feasible. In the absence of other forms of exclusivity like patent protection, nothing would prevent competitors from continuing to sell food or supplement products containing substances previously approved as being effective in treating a disease.

Another possible welfare loss (not illustrated in Figure 2) resulting from supplements being treated as drugs is that they indirectly increase the use of other clinically-proven approved drugs, which may be less safe or more expensive substitutes.

B. Structure/Function Claims

Recall that structure/function claims, in contrast to drug claims, allude to the relationship between a substance in a food or dietary supplement and the maintenance of normal body structure or functions in humans. Following *Pearson*, such claims must include a disclaimer that the product "is not intended to treat, cure or mitigate any disease." Structure/function claims are intended to suggest how a supplement may be useful in maintaining good health, while at the same time warning consumers that their efficacy in treating or preventing disease has not been demonstrated. Moreover, because such claims

[77] See *Claims*, *supra* note 33.

do not require pre-market authorization, they are sometimes said to be "unregulated" by the FDA.

To understand whether such a policy is efficient, consider that the main concerns from the regulator's perspective are that inefficacious supplements will be used by consumers to treat diseases that are unrelated to a nutrient deficiency (a type 1 error). On the other hand, there is also concern that certain supplements may not be used to maintain good health and or even prevent certain diseases (a type 2 error). It is therefore desirable for the regulator to have some degree of control over label statements so as to ensure that the product is not used to treat disease, while at the same time ensuring that manufacturers are free to suggest how a product might be helpful in maintaining good health.

From the consumer's perspective, products with such structure/function claims may be consumed in order to ensure an adequate supply of essential nutrients required for good health. In contrast to products with drug claims, consumers would continue to use such products in the absence of disease (e.g., the case of multivitamins), but not expect them to cure or treat a disease. These consumption patterns portray consumers as using supplements primarily to reduce type 2 errors. Type 1 errors are of little concern because the disclaimer advises consumers that such products should not be used to treat or prevent any disease.

What are the preferences for consumer free speech and instrumental choice under these circumstances? Consumers highly value a lessening of commercial free speech restrictions which would facilitate learning about the possible benefits of such products, thereby reducing type 2 errors. They also highly value the right to freely purchase such products (e.g., obtain them without prescription) since, for products that are GRAS, restrictions on distribution provide an unnecessary measure of safety.

The efficiency of a policy that allows structure/function claims with disclaimers is illustrated in Panel B of Figure 2. Being concerned primarily with type 2 errors, the consumer indifference curve is of the usual shape in which both free choice and commercial free speech rights (i.e., few labelling restrictions) are desirable "goods." The regulator's indifference curve on the other hand, is shown as a straight line. The regulator is relatively indifferent to restrictions on label statements and consumer free choice, because a well informed consumer is believed to be able to make decisions that minimize type 2 errors without increasing type 1 errors. This is so, because the disclaimer reduces the likelihood of a supplement being used to treat disease. Moreover, other counterfactual statements such as "these statements have not been evaluated by the FDA" advise the consumer of the possibility of type 1 error.

A straight line indifference curve indicates that the regulator can accomplish its goals of protecting the consumer through various combinations of restrictions on commercial free speech and prescriptive language indicating appropriate use of the product. Stated alternatively, free speech restrictions can be substitutes for restrictions to consumer free choice. For example, a product that carries a relatively "strong" claim of efficacy (a source of potential welfare loss due to type 1 error) can be made relatively innocuous if it

is accompanied by a strong disclaimer suggesting how the product should not be used. Alternatively, the disclaimer might suggest how other intervening factors may affect the efficacy of the product. (e.g., "may be helpful, when combined with a regimen of diet and exercise.") This arbitrage between fewer restrictions to commercial free speech and greater prescriptions on product use is represented in Panel B of Figure 2 as an upwards (north-western direction) movement along the regulator's indifference curve. Since it is a movement along the regulator's indifference curve, it results in no welfare improvement for the regulator.
However, for consumers, it results in a net welfare gain since the leftwards movement along the regulator's indifference curve creates a tangency at a higher level consumer indifference curve U'_C. Another way of seeing how a policy that allows disclaimers to be used is a welfare-enhancing policy is to note that in Panel B of Figure 2, the regulator's indifference curve coincides with the contract curve (though this is not a necessary condition for the result to hold).

The positive conclusion regarding the use of disclaimers in the case of structure/function claims is that they are efficiency enhancing. Disclaimers and other counterfactual statements can reduce type 1 error to the point where they are of no concern and further reduction commercial free speech rights would provide limited or marginal benefits to the regulator in the form of reduced type 1 or type 2 errors. Disclaimers are efficiency-enhancing policies when used in the context of structure function claims because providing additional information to consumers is, for the regulator, a more effective means of reducing costly type 1 errors than imposing restrictions on commercial free speech. A Pareto-efficient improvement occurs when disclaimers are used, because consumers highly value commercial free speech and will only commit a type 1 error if they know not to use supplements to treat disease.

The normative claim suggested by this analysis is that disclaimers should be used in situations where the potential gains from using products of unproven efficacy outweigh the known risks of inefficacy. The case of structure/function claims demonstrates that scientific uncertainty regarding the efficacy of a dietary supplement need not be regarded as negatively affecting consumer welfare. Policies to suppress efficacy statements based on inconclusive evidence are not always welfare-improving ones when the risks of type 1 error are small and can be mitigated simply by providing consumers with more information. An important caveat of the use of disclaimers is, however, that consumers are able to correctly interpret the meaning of scientific uncertainty and correctly weigh the potential benefits of supplement use against their costs.

C. Qualified Health Claims

Qualified health claims are the second set of claims put in place in order to reduce type 2 errors. In contrast to structure/function claims, they require pre-market authorization and may purport to treat or prevent disease if: 1) the relationship between a disease and a

substance is substantiated by evidence submitted to the FDA;[78] or 2) the claim is based on an authoritative statement of a U.S. scientific organization or the National Academy of Sciences; or 3) the claim includes qualifying language (e.g., "may" , "some scientific evidence suggest that…") intended to define the extent to which the statement is true.

As the following examples illustrate, qualifying language in health claims are intended to explain the limitations of the applicability of the claim or the degree of uncertainty regarding the available evidence.

> "Selenium may produce anticarcinogenic effects in the body. Some scientific evidence suggests that consumption of selenium may produce anticarcinogenic effects in the body. However, FDA has determined that this evidence is limited and not conclusive."[79]

> "Supportive but not conclusive research shows that eating 1.5 ounces per day of walnuts, as part of a low saturated fat and low cholesterol diet and not resulting in increased caloric intake, may reduce the risk of coronary heart disease. See nutrition information for fat [and calorie] content."[80]

The most remarkable aspect of such claims is that they admit counterfactual statements (e.g., "this evidence is limited and not conclusive"). Such statements are intended to reduce type 1 errors, the consequences of which may be the progression of a serious disease. Even so, because supplements can also be helpful in preventing disease (minimize type 2 errors), regulators also have an interest in ensuring that government restrictions do not completely dissuade consumers from using supplements. Counterfactual statements, when combined with a health claim, are therefore intended to encourage consumers to make informed choices that take into consideration their personal predispositions for type 1 and type 2 errors.

Panel C of Figure 2 illustrates how the welfare of both the consumer and the regulator are affected by control over commercial free speech and consumer choice. Indifference curves for both parties are similarly shaped, but more sharply curved than in the case of structure/function claims. The sharper curve indicates that commercial free speech and consumer free choice are both important to consumers, and that one may not be easily substituted in place of another. For consumers, a minimum level of regulatory control over efficacy statements is desirable in order to ensure that such products are not unintentionally used. Read literally, and without the disclaimer, the above statement regarding selenium, might persuade a cancer patient to use the product in lieu of other necessary treatment, thereby committing a serious type 1 error. Counterfactual

[78] Regulations developed as per the NLEA of 1990, requiring significant scientific agreement (SSA). *See supra* note 4 (regarding SSA).
[79] U.S. FOOD AND DRUG ADMINISTRATION, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, QUALIFIED HEALTH CLAIMS SUBJECT TO ENFORCEMENT DISCRETION (November, 2005) (visited July 4, 2006) <http://www.cfsan.fda.gov/~dms/qhc-sum.html>.
[80] *See id.*

statements and qualifying language are therefore important complements to claims of efficacy.

For regulators, health claims represent opportunities for consumers to interpret such (claims) as a cure for a serious disease for which the supplement may be inefficacious. As shown in Panel C of Figure 2, regulator preferences for commercial free speech and consumer free choice are therefore as they would be in the case of drugs. Regulators will prefer more control over commercial free speech than less, and will also prefer to direct consumer choice by suggesting when a product is unlikely to be of any benefit.

Based on these assumptions regarding the consumer and regulator, a regulatory regime that removes restrictions on commercial free speech would not be efficient. Consumers have little appreciation for an environment in which promoters would be free to make any unqualified statement, while regulators value such restrictions. Just as in the case of structure/function claims, a disclaimer or qualifying statement would be one means of increasing efficiency, in that qualifying statements could lessen the likelihood that a health claim results in a supplement being used to treat a disease for which the FDA has found no conclusive scientific evidence. It is moreover important to note that because both consumer and regulator indifference curves in this case are more sharply curved, a disclaimer policy produces a more important welfare improvement than in the case of structure/function claims. This is seen in Panel C of Figure 2, by the fact that the distance between the two indifference curves (owing to the curvature of the consumer indifference curve) is larger for the case of health claims than it is for the case of disease or structure/function claims.

Panel C also shows that the welfare improvement conferred by disclaimers and qualifying statements occurs by restoring an appropriate balance of commercial free speech and consumer free choice. In the absence of counterfactual statements and qualifying language, regulators, being concerned with type 1 errors, would be unwilling to lift restrictions on commercial free speech. This is shown as point A in Panel C. By combining counterfactual statements and qualifying language with health claims, however, type 1 errors are likely to be reduced because consumers will be better informed of the chances of a supplement being inefficacious. Under these circumstances, regulators are therefore willing to allow greater commercial free speech, as shown by the alternative equilibrium point B. At this point, consumer welfare is also improved because consumers are also better able to interpret the significance of health claims. In essence, the qualifying statements and disclaimers provide a welfare improvement, because the consumer willingly accepts some government direction (in the form of qualifiers and counterfactual statements), in exchange for a lessening of commercial free speech rights, which allows manufacturers to make greater claims of efficacy. This exchange of rights can be understood an efficiency enhancing exchange along the “contract curve” as illustrated in Figure 1.

The positive claim of this analysis is therefore that the FDA’s current position of approving health claims that do not meet the SSA standard with qualifying statements is efficiency-enhancing. However, an important caveat is that, while we assume that

qualifying language provides additional information that can both reduce type 1 and type 2 errors, it assumes that consumers are able to correctly interpret such information so as to be able to weigh the pros and cons of using a dietary supplement. The Federal Trade Commission has conducted some studies on how consumers interpret qualified health claims and finds that although consumers are able to understand that while qualified statements are based on less reliable scientific evidence, relatively strong language qualifying statements are likely to be necessary in order to effectively convey to consumers that the evidence does not meet the SSA.[81]

The normative claim emerging from this analysis is that qualified health claims should be permitted on the condition that the qualifiers and other counterfactual statements allude to the consequences of type 1 and type 2 errors. The qualified claim must therefore indicate that using a supplement to treat a serious disease, for which there is inconclusive evidence, can result in a worsening of a health condition due to lack of treatment. At the same time, manufacturers should be provided with incentives to produce more reliable scientific evidence in the form of a government ranking of available evidence. Such a system, presently under consideration,[82] essentially calls for qualifying language to be linked to the strength of available evidence. Under such a proposal, so called "second level" evidence would carry language such as "although there is scientific evidence supporting the claim, the evidence is not conclusive," while "forth level" evidence would carry claims such as "Very limited and preliminary scientific research suggests... FDA concludes that there is little scientific evidence supporting this claim."

V. CONCLUSION

Like many new technologies, dietary supplements create situations in which there are risks related to using them, but also risks from not using them as a result of exposure to preventable hazards (i.e., disease). Although a careful weighing of the costs and benefits of a new drug or supplement is in itself nothing new to the FDA approval process, only relatively recently, has there been reform in the manner in which regulatory agencies deal with incomplete information regarding potential risks and benefits.

This article strives to provide an economic analysis of the desirability of qualified health claims and FDA disclaimers. I argue that desirable regulatory policy should account for collective regulator and consumer interests under the circumstances under which dietary supplement are used. The Edgeworth box analysis presented here aims to illustrate that

[81] Comments from the Bureau of Consumer Protection, the Bureau of Economics, and the Office of Policy Planning of the Federal Trade Commission to the FDA (Jan. 26, 2004) (regarding food labeling, health claims, and dietary guidance) (No. 2003-0496) (last visited August 15, 2006) <http://www.ftc.gov/os/ 2004/01/040126fdacomments.pdf>.

[82] Letter from Dale Schoeller, President, *The American Society for Clinical Nutrition, Inc.*, to the FDA (Feb. 25, 2004) (concerning 21 C.F.R. § 101: food labeling, health claims, dietary guidance and advanced notice of proposed rulemaking) (No. 2003N-0496) (visited July 1, 2006) <http://www.ascn.org /fda healthclaims.pdf>.

disclaimers and qualified health claims – claims purported to create the most consumer confusion – are likely to be welfare maximizing forms of regulation when consumers intend to use them to prevent or treat disease. In welfare terms, such a regulatory institution is "efficient" in the sense that it maximizes collective regulator and consumer interests.

Disclaimers and qualified statements improve the efficiency of the regulatory system by reducing market failures resulting from incomplete information. In urging governments to regulate supplements as drugs, critics of the DSHEA have failed to appreciate that all-or-nothing prescriptions for regulatory control can do more to reduce consumer welfare by impeding access to useful products without necessarily improving safety in a manner that offsets these losses.

However, these conclusions rest on important assumptions that may be understood as important caveats. First, is that consumers have a predilection for maintaining commercial free speech rights of sellers. The facts in *Pearson v. Shalala* suggest that consumer and supplement promoter interests were perfectly aligned, because in that case supplement promoters argued that it was in the consumers' best interest to permit supplement promoters to make efficacy statements based on supportive, but inconclusive evidence, in order to reduce type 2 errors.

Second, as mentioned above, is that consumers are able to correctly interpret qualified statements and disclaimers. Although my model distinguishes three different regulatory regimes for supplements, in practice, most consumers are likely to have difficulty in distinguishing the material differences between structure/function and qualified health claims. It remains unclear whether consumers view maintaining good health and preventing disease as the same thing.

Finally, although disclaimers are portrayed as providing direction, they don't always provide the direction that shapes consumer choice, in the manner suggested by the "contract curve" in the Edgeworth box analysis. Lessened restrictions on commercial free speech may therefore not always be compensated adequately by stronger disclaimers if the latter do not provide sufficient direction on appropriate use of the product. In this sense, stronger claims when combined with stronger disclaimers, may not always be more efficient in promoting social welfare where the main concern is type 2 error. These caveats do not, however, undermine the central proposition that stronger claims of efficacy when combined with more specific disclaimers, can be welfare-enhancing regulatory instrument.

List of Figures

Figure 1

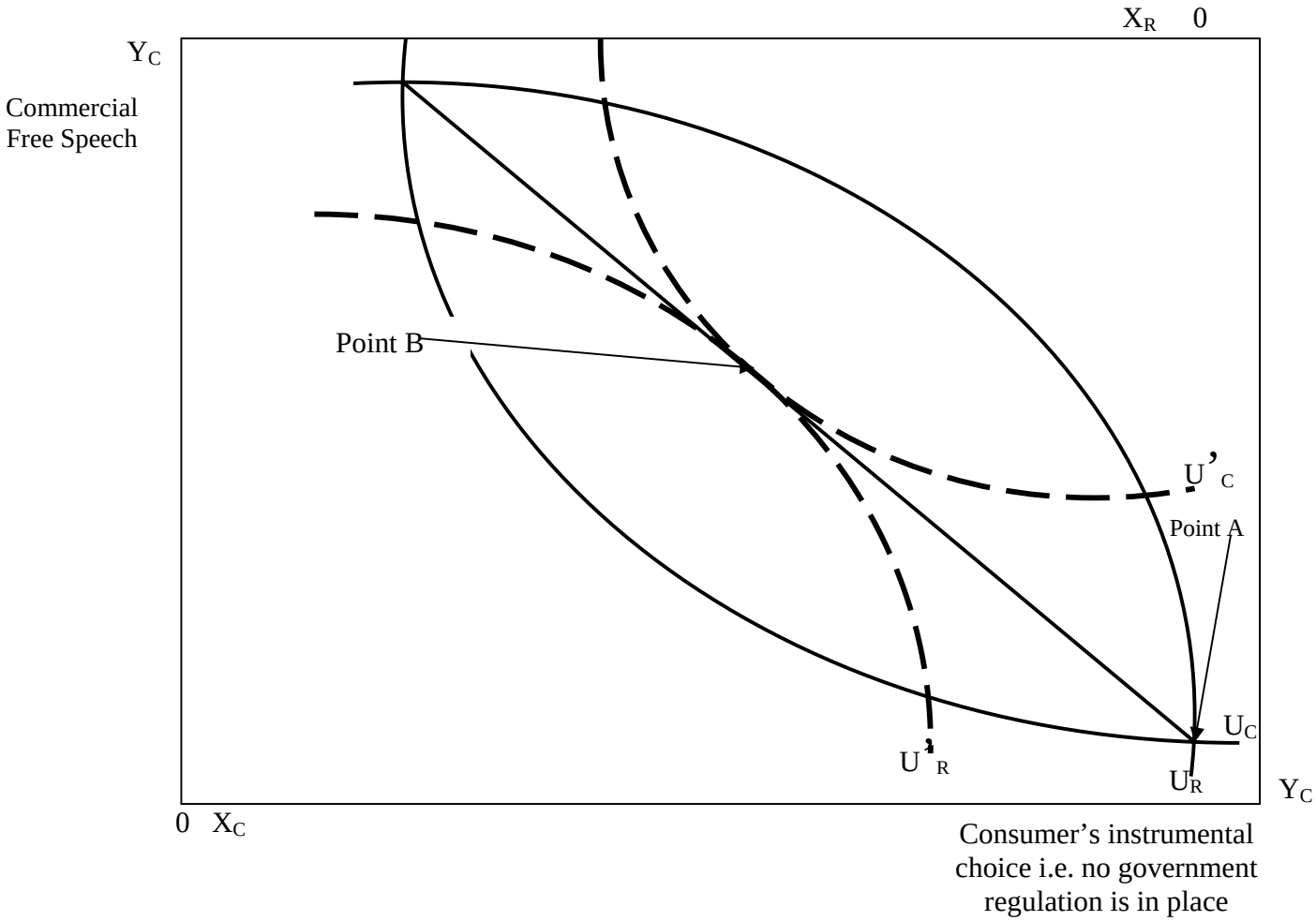
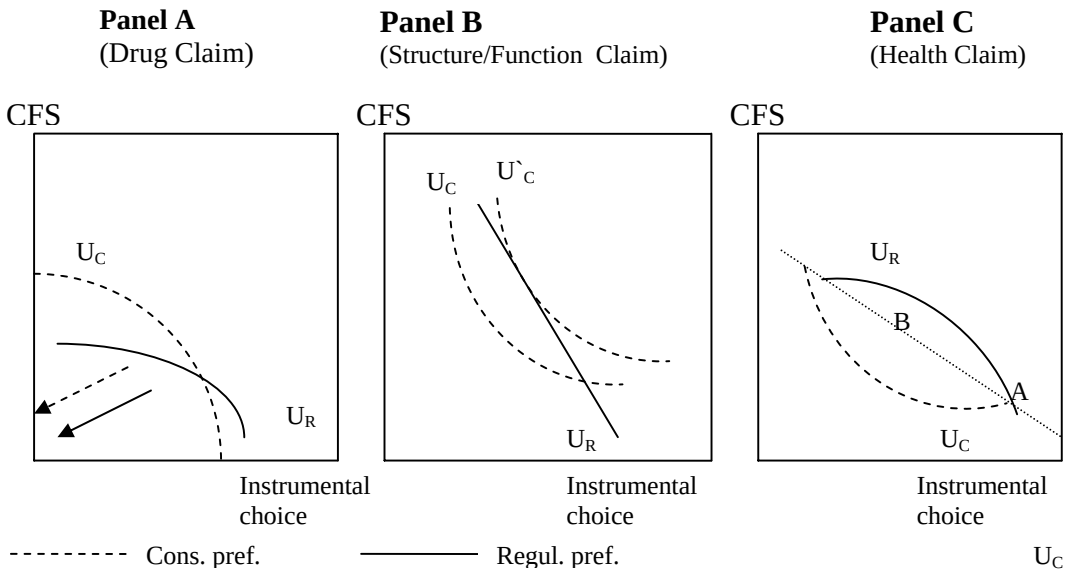


Figure 2


Panel A
(Drug Claim)
Panel B
(Structure/Function Claim)
Panel C
(Health Claim)
CFS
CFS
CFS
U_C
U_R
U_C
$U`_C$
U_R
U_R
B
A
U_C
Instrumental choice
Instrumental choice
Instrumental choice
Cons. pref.
Regul. pref.
U_C

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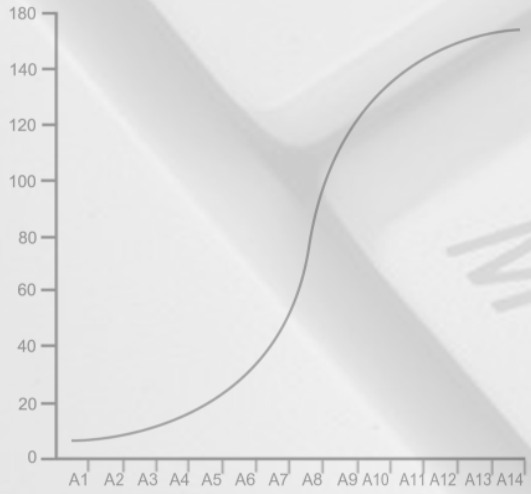

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