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Cheaters Shouldn't Prosper and Consumers Shouldn't Suffer: The Need for Governmental Enforcement Against Economic Adulteration of 100% Pomegranate Juice and Other Imported Food Products

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I. Introduction

In the modern global food system – marked by the trade flow of a variety of food 
products and ingredients from multiple locations in the world – economically motivated 
adulteration has emerged as a growing menace that threatens the health and well-being of 
consumers, the economic livelihoods of honest purveyors of food in the global marketplace, and 
the integrity and viability of national food regulatory systems. Economic adulteration is a form 
of cheating that includes padding, diluting, and substituting of food product. Although this 
cheating is rooted in past food systems, the new paradigm for economic adulteration – a vast 
international food-trade system – increases the level of fraud, especially for imported premium 
products that are susceptible to fakery, such as olive oil, honey, supplements, and pomegranate juice.

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2 See AT Kearney and Grocery Manufacturers Association, Consumer Product Fraud: Deterrence and Detection, i (2010).

3 Observed Robert Brackett, former director of the FDA’s Center for Food Safety and Applied Nutrition, “[n]ever 
before in history have we had the sort of system that we have now, meaning globalization of the food supply.” 
Andrew Bridges, Imported food rarely inspected, USA TODAY (Apr. 16, 2007), 
The public-health hazards of economic adulteration are demonstrated most poignantly by the recent melamine scandal in China that rocked consumer confidence world-wide. Melamine is a widely used chemical found in hard plastic dishes and the linings of food containers. The chemical made international headlines when a 2007 investigation into Chinese pet food revealed that, in addition to sickening and killing pets, melamine could also be harmful to humans under certain circumstances. The investigation found that the addition of melamine to infant formula by Chinese milk dealers and suppliers, in an effort to increase protein content and profits, resulted in 50,000 infant hospitalizations and six tragic infant deaths in China. Following an initial denial, China accepted responsibility for regulatory laxities and inconsistencies that led to the melamine tragedy. The Chinese government prosecuted, convicted, and imposed harsh sentences on those involved, including execution for the director of the Food and Drug Agency, who was convicted of accepting bribes to allow defective food product on the market. China also executed a dairy farmer and a milk salesman for their roles in the sale of contaminated infant formula.

5 Id.
6 Id.
7 Id.
The dynamic that gave rise to such a horrific case of economic adulteration and a slow response from the government, only to be followed by the imposition of harsh penalties, reflects a food and regulatory culture unique to China – a massive food industry with small, scattered operations; a close relationship between local governments and food operators that shields wrong-doers from punishment; a new national food safety law that still needs more time to be fully implemented; and a national government that is able both to conceal critical public-health information and, when it chooses, punish responsible persons quickly and severely.\textsuperscript{11} Government enforcement against economic adulteration, whether in China or elsewhere, has fluctuated through the centuries depending on the legal system, the regulatory culture, and on the resources and priorities of the regulatory bodies.\textsuperscript{12} For example, the United States’ resource-strapped Food and Drug Administration (FDA) – the regulatory body with jurisdiction over the safety and quality of imported food – has not made economic adulteration a priority for several years. As a consequence, economic adulteration within the national food system now flourishes largely unchecked by regulatory enforcement.\textsuperscript{13}

Despite its entrenched regulatory inertia, the recent melamine problems in China have caused the FDA to reconsider the public-health consequences of non-action against economic adulteration. A public hearing on economic adulteration in mid-2009 reflects the FDA’s specific concern for melamine-type incidents and a general recognition that the global food system

\textsuperscript{11} See id.

\textsuperscript{12} See generally Jessica Vapneck & Melvin Spreij, Perspectives and Guidelines on Food Legislation, With a New Model Food Law 67-109 (FAO 2005) (discussing the of myriad of factors that influence national food regulatory frameworks).

provides an even larger and more effective platform for cheaters. The FDA’s engagement raises two fundamental questions: first, whether the FDA adequately appreciates the full range of costs associated with the emerging problem of economic adulteration from food and ingredient products; and second, whether the agency can and will move beyond recognition of the problem and enforce against food fraud in imported food products.

This article addresses these two issues through the prism of a modern, premium beverage developed in the United States – 100% pomegranate juice, made of concentrate with no added sugar, additives, or preservatives. There are several reasons for selecting 100% pomegranate juice as the prism. First, the product represents a unique, healthy, and nutritious food source – the sort of product that governments should want to promote for consumers and protect against adulteration. Second, the economic adulteration of 100% pomegranate juice showcases the insidious problem of adulterated imported food product in the global food system. Third, the specific question of enforcement against adulterated 100% pomegranate juice effectively raises the general question of the ideal role of the FDA’s enforcement powers in a complex, international food supply. The unacceptable life-threatening costs associated with adulterated pet food and infant formula in China make a compelling case for government enforcement. There should be full accountability and vigorous enforcement against cheating that causes such suffering, especially to innocent infants and their families. Fortunately, while the adulteration of 100% pomegranate juice is extensive, it does not present immediate safety risks like tainted milk did in China. This article asserts that the lack of an immediate and discernable safety threat, however, should not relegate enforcement against adulteration to a low priority for the FDA, as it is today. Economic adulteration that compromises the value of otherwise healthy and nutritious

food and beverage products raises significant costs that should be weighed by public-health agencies in grappling with the outcomes of a complex, global food system.

Thus, it is through the prism of pomegranate juice that this article frames a three-part analysis of government enforcement against economic adulteration as it has emerged in the modern global food trading system. First, this article briefly introduces 100% pomegranate juice and its impressive health benefits, largely due to the polyphenol antioxidants found in the juice, and the economically-motivated adulteration of pomegranate concentrate outside the United States that is sold in the United States as 100% pomegranate juice to unsuspecting consumers. 15 Second, to provide a useful backdrop for the regulatory inertia by the FDA towards this type of food fraud, this article chronicles the history of government enforcement against economic adulteration, including an assessment of the effect of globalization on economic adulteration and the FDA’s recent recognition of the product-safety challenges from economic adulteration in the world-food-trade system. Third, this article addresses what should be the appropriate enforcement-role by the FDA towards economic adulteration of imported food product. This role will be evaluated in terms of available enforcement tools and the far-reaching public-health, economic, institutional, and social costs of non-enforcement against economically-motivated adulteration of imported premium and otherwise healthy and nutritious products like pomegranate concentrate. This article concludes that a more sound appreciation for the broader costs of economic adulteration would help elevate the priority of enforcement by the FDA against this form of food fraud.

While this article benchmarks the costs of non-enforcement against imported pomegranate concentrate, it also creates context in which to evaluate the role of regulation in the policing of a complex global food system. It is within this broader context that important policy questions crystallize. What is the FDA’s role in the global food system? How does the FDA engage in a cost-analysis that fully appreciates the implications of problems such as economic adulteration, which raise immediate food safety concerns, but also other problems that, if unaddressed, threaten the very viability of the regulatory system whose mission it is to protect public health? How will the FDA garner resources and commitment to solve sophisticated and institutional problems such as economic adulteration? While this article may not fully answer these questions, discussing the issues themselves is an important step in a full and open analysis of the quality and safety of the global food supply.

II. Economic Adulteration of Pomegranate Juice

A. Pure Pomegranate Juice: A Drink to Good Health

An introduction to pomegranate juice starts with the pomegranate itself, a highly-valued, tantalizing fruit with a festive color and delectable taste. Bearing the Latin name, Punica granatum, the pomegranate grows on a fruit-bearing deciduous shrub or small tree that stands between fifteen to twenty-feet tall. The dimensions of the pomegranate fruit are similar to that of an apple. It has a smooth, leathery skin that varies in color from brown or brownish yellow to shiny red. The inside of the fruit contains edible juicy pulp and hundreds of small, edible seeds.

18 KIPLE & ORNELAS, supra note 16, at 1837.
Cultivation of the pomegranate began in Persia approximately 5000 to 6000 years ago, but later spread to ancient Egypt, India, Afghanistan, and China. The pomegranate was grown in the famous hanging gardens of Babylon and was introduced into Rome by way of Carthage. From Rome, the pomegranate emerged in early Christian-Europe to become a celebrated religious decoration. Following the conquest of Mexico by Cortez in 1521, Jesuit missionaries introduced pomegranates into Mexico and then carried them northward and planted the perdurable fruit in the California mission gardens. The pomegranate has now secured an important and distinctive place in California, where the planting of pomegranate trees has doubled in three years to 29,000 acres in 2009.

There are various edible uses of pomegranates. In addition to being eaten fresh, the fruit has historically been made into sauces and desserts. It is also commercially produced into grenadine syrup, which is employed around the world to flavor milk, drinks, desserts, soda, lemonade, and cocktails. The recent popularity of pomegranates has proliferated commercial uses of the fruit. Pomegranates and pomegranate extract are frequently included in food items

19 Id.
20 Id.
25 See KIPLE & ORNELAS, supra note 16, at 1838.
such as juices, ice cream, sorbet, candy, chocolate, coffee, tea, natural-bars, and supplements, and non-food items such as skin care, lotion, cosmetics, soap, sanitizers, and shampoo. Amongst the array of commercial products, one particularly exceptional pomegranate product stands out – 100% pomegranate juice.

The recent dramatic growth of consumer demand for pure pomegranate juice is driven largely by the promise of health benefits. Over eighty-one percent of consumers now consume pomegranate juice because of its health benefits. Reader’s Digest calls pomegranate juice, “the closest thing to a miracle in a bottle we’ve found yet,” because of pomegranates’ high antioxidant levels — more than any known fruit except the acai. Antioxidants are substances that neutralize free radicals — atoms or molecules lacking an electron that “collide with other molecules in an attempt to steal an electron” — by binding with them and inhibiting oxidation. Many different substances can be considered antioxidants, but pomegranate juice contains polyphenol antioxidants, which are among the most powerful. In fact, the polyphenols found in pomegranate juice have superior health benefits to whole pomegranate fruit before juicing. Medical and scientific research shows that pomegranate juice can help combat cardiovascular


27 See presentation materials provided to FDA on Sept. 3, 2009, by Pure PJ (Partnership for Unadulterated, Real, and Ethical Pomegranate Juice), comprised of U.S. pomegranate growers and juice processors (on file with author).


29 See ROBERT A. NEWMAN AND EPHRAIM P. LANSKY, POMEGRANATE THE MOST MEDICINAL FRUIT 18 (Basic Health Publications, Inc. 2007).


31 Id.

32 Krueger, supra note 15.
disease, cancer, and erectile dysfunction, and suggests possible benefits for people with diabetes and Alzheimer’s disease. There is also a possibility that pomegranate juice may reduce swelling in hemorrhoids or help cure diarrhea.

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33 See de Nigris, F. et al., Pomegranate juice reduces oxidized low-density lipoprotein downregulation of endothelial nitric oxide synthase in human coronary endothelial cells, Nitric Oxide 15, 259-63 (2006) (100% pomegranate juice prevents the build up of plaque in the arteries); Sumner, M. et al., Pomegranate juice improves myocardial perfusion in coronary heart patients, American Journal of Cardiology, 96, 810-814 (2005) (patients drinking eight ounces of 100% pomegranate juice daily demonstrated a 17% improvement in blood flow to the heart after three months); Aviram, M. et al., Pomegranate Juice Consumption for 3 Years by Patients with Carotid Artery Stenosis Reduces Common Carotid Intima-Media Thickness, Blood Pressure and LDL Oxidation, Clin. Nutr. 23, 423-433 (2004) (pilot study showed a 30% decrease in arterial plaque in patients who drank eight ounces of 100% pomegranate juice every day for one year, compared to a 9% increase in arterial plaque among patients drinking no pomegranate juice and showed that consuming pomegranate juice daily for one year can lower a hypertensive patient’s systolic blood pressure by 18%); Aviram, M. and Dornfeld, L., Pomegranate juice consumption inhibits serum angiotensin converting enzyme activity and reduces systolic blood pressure, Atherosclerosis, 158, 195-198, (2001) (pomegranate juice can reduce atherosclerosis, the process in which material build up causes artery walls to thicken).

34 See Pantuck, A. et al., Phase II Study of Pomegranate Juice for Men with Rising Prostate-Specific Antigen following Surgery or Radiation for Prostate Cancer, Clinical Cancer Research 12, 4018-4026 (2006) (patients who consumed eight ounces of 100% pomegranate juice daily for two years dramatically reduced their Prostate-Specific Antigen doubling times – an indicator of disease progression – from 15 months to 54 months); Seeram, N. et al., In vitro antiproliferative, apoptotic and antioxidant activities of punicalagin, ellagic acid and a total pomegranate tannin extract are enhanced in combination with other polyphenols as found in pomegranate juice, J. Nutr. Biochem., 16, 360-67 (2005) (pomegranate juice’s purified ellagitannins (antioxidants) can inhibit the proliferation of apoptosis -- a series of cellular events resulting in death -- in colon cancer cells); Kim, N. et al., Chemopreventive and adjuvant therapeutic potential of pomegranate (Punica granatum) for human breast cancer, Breast Cancer Res. Treat., 71, 203-17 (2002) (anti-proliferative effects of pomegranate juice inhibit breast cancer cell lines).

35 See Forest C. et al., Efficacy and safety of pomegranate juice on improvement of erectile dysfunction in male patients with mild to moderate erectile dysfunction: a randomized, placebo-controlled, double-blind, crossover study, International Journal of Impotence Research 19, 564-567 (2007) (pilot study showed that men who consumed eight ounces of 100% pomegranate juice for four weeks were 50% more likely to have an improved erection than men taking a placebo).

36 See NEWMAN, supra note 29, at 73 (by no increasing blood sugar levels in adults, pomegranate juice may help people with diabetes).

37 See id. at 30 (demonstrating that pomegranate juice may lead to superior performance in animals suffering from Alzheimer’s disease by preventing the accumulation of harmful beta amyloid deposits on the neurons).

38 See id. at 31-32.

The promotion of pomegranates’ health benefits by a beverage company using adulterated pomegranate juice concentrate originating from outside the United States led to a decision in 2007 by the U.S. District Court in the Central District of California in favor of POM Wonderful in its lawsuit against Purely Juice, Inc.\textsuperscript{39} POM Wonderful is the largest grower and distributor of pomegranates and pomegranate juice in the United States, growing and distributing the Wonderful variety of pomegranates and 100\% pomegranate juice containing no added sugars or preservatives.\textsuperscript{40} The recorded findings of the District Court confirm the unique development and value of 100\% pomegranate juice. First, the court found that “aware of the nutritional and health benefits associated with pomegranates, and sensing that an untapped market might exist, the founders of POM Wonderful LLC embarked on a strategic plan to bring this ancient fruit to the attention of the American consuming public.”\textsuperscript{41} Second, the court noted that POM Wonderful’s strategy “included the investment of millions of dollars on scientific research of the health benefits of pomegranates and pure pomegranate juice.”\textsuperscript{42} Third, the court found persuasive the scientific research that showed 100\% pomegranate juice provides cardiovascular benefits, inhibits “prostate cancer, as well as numerous chronic diseases associated with aging such as heart disease, Alzheimer’s disease, and dementia.”\textsuperscript{43} Fourth, the court found that these health benefits are based on the use of 100\% pomegranate juice containing no added sugars or


\textsuperscript{40} Id. at *2-3.

\textsuperscript{41} See id. at *1.

\textsuperscript{42} See id. at *2.

\textsuperscript{43} See id. at *1.
preservatives and that the presence of indeterminate adulterants undermines these benefits.\textsuperscript{44} Fifth, the court noted the media and consumer recognition of POM Wonderful, including television newscasts, cooking and lifestyle shows, and innovative marketing campaigns.\textsuperscript{45} Sixth, the court determined that the investment of millions of dollars to research and promote the nutritional qualities and health benefits associated with pure pomegranate juice created the burgeoning market for 100% pomegranate juice.\textsuperscript{46} Seventh, the court concluded that “Pom Wonderful’s pomegranate juice has, in less than six years, eclipsed all other products in its market segment of super premium juices to take the top spot nationwide in supermarket sales . . . .”\textsuperscript{47}

In April 2006, Purely Juice, a competitor of POM Wonderful in the bottled pomegranate juice market, began marketing and selling a beverage labeled “100% pomegranate juice.”\textsuperscript{48} Unlike POM Wonderful, who grows its own pomegranates, Purely Juice secured pomegranate juice concentrate from foreign suppliers in Iran and other Middle Eastern countries.\textsuperscript{49} In 2007, POM Wonderful filed a federal lawsuit against Purely Juice claiming that the company was deceiving consumers by selling adulterated pomegranate juice. The court agreed with test results from seven different laboratories which concluded that Purely Juice’s juice could not have been 100% pomegranate juice since it contained foreign sugars, colorants, and filler juices.\textsuperscript{50} The

\textsuperscript{44} See id. at *1.
\textsuperscript{45} See id.
\textsuperscript{46} See id.
\textsuperscript{47} See id. at *2.
\textsuperscript{48} Id. at *3-4.
\textsuperscript{49} Id. at *5.
\textsuperscript{50} See id. at *4.
court found that “it was widely known in the super premium juice industry that there were serious issues of adulteration with pomegranate juice concentrate originating from outside the United States.”

The court determined that Purely Juice engaged in false advertising and misleading marketing and ordered Purely Juice to pay an approximate $1.5 million in damages.

The problem of cheating by manufacturers and suppliers in the juice industry, addressed in Purely Juice, is known as economic adulteration. Economic adulteration involves substituting something of a lesser value for something of higher value and then passing off the product as one of higher value; for example, adding color to trout and falsely calling it salmon. The substituted goods that are of a lesser value are generally cheaper, inferior ingredients.

The incentives for economic adulteration of food and beverages are predictably economically related. The first and most obvious motivation for food manufacturers is to increase profits. A manufacturer may use cheap filler that is easily disguised to increase the volume sold thereby cutting the cost and increasing the ultimate profit margin. Another incentive is competition. If a manufacturer cannot meet a customer’s quality criteria it may adulterate the product in an attempt to either meet a specification or to compete by offering an admittedly inferior product at a lower price. Customers who are not aware of the adulteration

51 Id. at *5.
52 See id. at *14-15.
54 Id.
56 See id.
may wind up believing they are getting a bargain. Economic adulteration may also be market driven, resulting from pressure to cut costs. As customers squeeze their suppliers to reduce costs, there comes a point when the supplier may adulterate the product to lower the cost and maintain a workable margin. Incentives for economic adulteration in the world food and beverage market are especially appealing for higher-value food products, such as 100% pomegranate juice. Pomegranate juice concentrate is in high demand – due to its well documented health benefits and other special qualities – and in short supply. The result is costly pomegranate concentrate, especially in comparison to apple, orange, and grape juice. These incentives tempt unprincipled foreign exporters to extend limited supplies by adulteration.

The adulteration of foreign 100% pomegranate concentrate is accomplished by using cheap ingredients that are manipulated depending on the goals of the cheater. The ingredients can be organized in four categories. First are sweeteners, including cane and beet sugars, high fructose corn syrup, and filler fruit juices, such as apple, white grape, and pear. The advantage of these fillers is that they are a clear and often unnoticeable sugar substitute. Second are

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57 See id.

58 See id.

59 See id.


61 See presentation materials provided to FDA on Sept. 3, 2009, by Pure PJ (Partnership for Unadulterated, Real, and Ethical Pomegranate Juice), comprised of U.S. pomegranate growers and juice processors (on file with author).

62 See id.

63 See id.
flavoring agents, such as citric acid. The purpose of flavoring agents is to pull up the unique, tart flavor of pomegranate juice that is lost from the inclusion of fillers. Third are coloring agents, including black currant, aronia, elderberry, grape pigment, cherry, and raspberry. These coloring agents substitute for the natural pomegranate color. Where filler fruit juice concentrate is used in place of pomegranate concentrate, these flavoring and coloring agents are employed to help disguise the adulteration. For example, a small measure of aronia can go a long way to rectify coloring deficiencies when a large measure of cheap apple juice replaces pomegranate juice in concentrate. The fourth category consists of tannins, including grape skin and extract, which are used to replace the astringent, antioxidant properties that are lost because of adulteration. A combination of these cheap ingredients is used in various ways to orchestrate the fraud.

III. Regulatory Response to Economic Adulteration

A. History Tour

Economic adulteration is not new, nor is it unique to 100% pomegranate juice. Food fraud in the form of economically motivated adulteration has been an interminable scar on food commerce throughout history. It has involved basic food staples such as wine and bread, as noted in Isaiah: “Wherefore do ye spend money for that which is not bread?” Goods that have been commonly masqueraded as something else include seafood, olive oil, honey, maple syrup, 

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64 See id.
65 See id.
66 See id.
67 Isaiah 55:2.
and vanilla. Economic adulteration is not only a story about cheating, but also about governments’ responses to the dishonesty. It raises the general question of governmental will and commitment to enforce against economic adulteration and the specific question of how a government can successfully employ its resources to stop cheaters who continue to devise new, innovative, and sophisticated methods of cheating.

1. **Graeco-Roman Society**

The first stopping point in a historical tour of economic adulteration is the Graeco-Roman society. The Greek botanist Theophrastus (370-295 BC) reported the use of artificial flavors in the food supply and on the use of adulterants for economic reasons in some items of commerce. As documented by Pliny the Elder (23-79 AD) and the physician Galen (131-201 AD), a sizeable trade in foods from the Mediterranean and beyond brought economic food adulteration to Rome. Food products in Rome that were particular targets of adulteration included grains, spices, wine, and preservatives. Romans worried about economic adulteration of food not just because of the fraud, but also because they realized that foods could be tampered with in such a way to endanger the health of Roman consumers. As Pliny complained, “so many poisons are employed to force wine to suit our taste – and we are surprised that it is not wholesome!”

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69 See Reay Tannahill, *Food in History* 293 (Three Rivers Press 1988).

70 See Spice, *supra* note 55.

71 See id.


73 Id.

74 Id.
Roman law recognized food fraud and, through limited imperial decrees, attempted to regulate markets to protect citizens from crooked merchants.\textsuperscript{75} Under fraud laws, those who engaged in the fraudulent sale of food were subject to private rights of action.\textsuperscript{76}

2. Middle Ages in Europe

Another stopping point is Europe during the Middle Ages, where staple foods like meat, bread, and wine were targets for adulteration. The “medieval nose” was particularly sensitive to the smell of decay, and was used to catch suppliers of putrid meat.\textsuperscript{77} Bread was more difficult to manage, as catching a wily baker could be a challenge.\textsuperscript{78} Cheating bakers sold underweight bread, the price of a loaf being fixed in relation to its weight.\textsuperscript{79} Such cheating led to regulations like the “Assize of Bread and Ale,” which dictated what went into everyday food goods.\textsuperscript{80} Guilds comprised of “ale conners, pepperers, and garblers” enforced these purity laws with considerable effectiveness.\textsuperscript{81} A particular enforcement action suited to the sensibilities of early fourteenth-century London, was used against bakers selling underweight bread: the offending loaf would be slung around the neck of the condemned baker and he would be drawn through the

\textsuperscript{75} Id. at 573.

\textsuperscript{76} Id.

\textsuperscript{77} TANNAHILL, supra note 69, at 162.

\textsuperscript{78} Id. at 163.

\textsuperscript{79} Id.

\textsuperscript{80} See BEE WILSON, SWINDLED: THE DARK HISTORY OF FOOD FRAUD, FROM POISONED CANDY TO COUNTERFEIT COFFEE 67 (Princeton University Press 2008).

\textsuperscript{81} Id.
dirtiest streets in town on a mobile pillory to be jeered at and targeted by flying debris hurled from fellow citizens.\textsuperscript{82}

3. \textbf{Industrialized England}

Industrialization increased the scope and sophistication of economic adulteration. Tay Tannahill, in her book \textit{Food History}, notes that food manufacturers have always practiced adulteration on a limited and local scale, “but the growth of towns and the expansion of roads and railways brought into being an organized food industry that was not equipped to cope with the problems of handling transport and availability of raw materials.”\textsuperscript{83} Bee Wilson, in her recent book, \textit{Swindled: The Dark History of Food Fraud, From Poisoned Candy to Counterfeit Coffee}, posits that adulteration went hand in hand with the rise of industrialized capitalism.\textsuperscript{84} Wilson’s story begins in England, which was the first country to simultaneously urbanize and embrace laissez-faire economic policies.\textsuperscript{85} In the process, the elaborate regulatory system conceived in medieval times to control food adulteration gradually crumbled in the eighteenth and nineteenth centuries.\textsuperscript{86} As the power of the guilds waned and urban entrepreneurs gained greater control of the market, the buying and selling of food came to be ruled by the law of caveat emptor.\textsuperscript{87} “It was a ‘buyer beware’ culture,” Wilson laments, one that “foisted huge responsibility onto a population that lacked even basic democratic rights.”\textsuperscript{88}

\textsuperscript{82} TANNAHILL, supra note 69, at 163-64.

\textsuperscript{83} Id.

\textsuperscript{84} See WILSON, supra note 80, at 13.

\textsuperscript{85} See e.g., id. at 19-20, 34.

\textsuperscript{86} See id. at 85-89.

\textsuperscript{87} Id. at 34.

\textsuperscript{88} Id. at 95.
Notwithstanding Industrial Era governments’ failure to control food adulteration, many enterprising scientists exposed cases of food fraud to the public. In 1820, German-born chemist Friedrich Accum published *A Treatise on Adulterations of Food, and Culinary Poisons*. The text contained startling revelations about adulteration in the English food system, including vinegar mixed with sulfuric acid, pickles colored with copper, sugary confections dyed red with lead and pepper mixed with floor sweepings. Following allegations of theft from the Royal Science library, Accum was forced to leave the country in shame. However, the proverbial cat was out of the bag. In 1850, discerning a public appetite for the truth about food, Dr. Arthur Hill Hassall, a chemist, and Dr. Henry Lethaby, a dietician, published a series of articles in England reporting on the extraneous matter found in samples of food products they randomly purchased in London shops. With the aid of a microscope, they uncovered disturbing fraudulent practices. Their findings showed that loaves of bread were adulterated with alum, a mineral-salt whitening agent, and that coffee was diluted with chicory, acorns, or a type of beer.

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89 *See Fredrick Accum, A Treatise on Adulterations of Food, and Culinary Poisons* (2nd ed. 1820).

90 *Id.* at 300.

91 *Id.* at 298.

92 *Id.* at 305.

93 *Id.* at 286.

94 *See Wilson, supra* note 80, at 39-45.

95 *See id.* at 1-45 (providing an excellent summary of the “glorious” career of Fredrick Accum). Ms. Wilson dramatizes Accum’s place in food history by stating that “[i]n the history of food adulteration, there are two stages: before 1820 and after 1820; before Accum and after Accum.” *Id.* at 1.

96 *See Tannahill, supra* note 69, at 294.

97 *See Wilson, supra* note 80, at 119-24.
called mangelwurzel. Hassall worked with Thomas Wakely, founder and editor of the *Lancet*, to publish the names and addresses of the shops selling adulterated goods. A few savvy manufacturers soon recognized that the new focus on purity might pay dividends. When Hassall praised provisioner Crosse & Blackwell for no longer adding copper to its pickles, the company began to market their products as “natural.” Wilson reports, “purity became a marketing device; and it has been so ever since.” Not leaving the dealing of economic adulteration solely to enterprising scientists and the marketplace, the government responded in 1860 by enacting the first comprehensive English food safety legislation, the Adulteration of Food and Drink Act.

B. U.S. Regulatory Response

1. Early Years

The United States went through much the same historical trajectory as Britain. Prior to passage of the Food and Drug Act, early food laws were limited to state and local regulation — there was no federal control over the processing of food. In the last half of the nineteenth century, problems associated with food safety began to develop as food production shifted from the home to the factory. Developments in chemistry facilitated this shift, bringing

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98 Tannahill, *supra* note 69, at 294.

99 Wilson, *supra* note 80, at 124-32.

100 Id. at 143.

101 Id.

102 23 & 24 Vict. C. 84. Although the Act is referred to as the first modern food regulatory statute, it was rarely enforced and real changes in food regulation did not come until additional legislation was adopted in 1875. Charles Lister, *Discord and Change: An Assessment of the European Community's Food Packaging Laws*, 48 FOOD & DRUG L.J. 589, 629 n.4 (1993).


104 Id. at 5.
advancements in food science and new food additives, colorings, and means of adulteration.\textsuperscript{105} The lack of government regulation led to tampering with products by substituting cheap ingredients for those represented on labels.\textsuperscript{106}

The tampering of food for an economic advantage led to a serious milk-contamination problem in New York City in 1858 that was recently retold in an op-ed contribution to the New York Times by Bee Wilson.\textsuperscript{107} According to Wilson, the increase from 90,000 to 120,000 quarts of milk a day entering New York City in the 1850s was due to dairies padding their milk with water, and then restoring its richness with flour.\textsuperscript{108} In time, however, the preferred adulterant became “swill milk, a filthy, bluish substance milked from cows tied up in crowded stables adjoining city distilleries and fed the hot alcoholic mash left from making whiskey.”\textsuperscript{109} Wilson notes that the mash itself was doctored “with plaster of Paris to take away the blueness, starch and eggs to thicken it and molasses to provide a buttercup hue of honest Orange County milk.”\textsuperscript{110} This deliberate economic adulteration reportedly killed up to 8,000 children in a year.\textsuperscript{111}

Dr. Harvey Wiley entered the food world to combat contemporary emerging problems like “swill milk,” and left his stamp firmly on the development of food law in the US. In 1883, Dr. Wiley became the chief chemist of the U.S. Bureau of Chemistry, which was then part of the

\textsuperscript{105} Id.
\textsuperscript{106} Harvey W. Wiley: Pioneer Consumer Activist, FDA Consumer Magazine (Jan-Feb 2006), available on FDA Web site at \url{http://www.fda.gov/AboutFDA/WhatWeDo/History/CentennialofFDA/HarveyW.Wiley/ucm081121.htm}.
\textsuperscript{107} Bee Wilson, The Swill is Gone, NY TIMES (Sept. 29, 2008), available at \url{http://www.nytimes.com/2008/09/30/opinion/30wilson.html}.
\textsuperscript{108} Id.
\textsuperscript{109} Id.
\textsuperscript{110} Id.
\textsuperscript{111} Id.
United States Department of Agriculture (USDA). Dr. Wiley expanded research and testing of food and documented the widespread adulteration of foods. He helped spur public concern over food safety and quality by his publications and by campaigning for a national food and drug law. Wiley specifically focused on chemical preservatives as adulterants through his highly publicized “poison squad, comprised of young men who tested the effects of chemicals and adulterated food on themselves.”

At the turn of the century, another important figure in the development of food law emerged on the U.S. scene – Upton Sinclair. As a muckraking journalist, Sinclair published his book *The Jungle* in 1905. Sinclair’s novel was set amid the wretched working conditions of Chicago’s meat packing plants. While Sinclair’s intent was to expose the “inferno of exploitation” of the typical American factory worker, the food safety concerns are what piqued public attention. *The Jungle* portrayed nauseating practices and unsanitary conditions in the meat-packing industry. Sinclair described diseased and rejected meat products, where mounds of meat were stored in great piles under leaky roofs and layers of dried rat dung. This portrayal captured the public’s attention and focused food safety regulations squarely on the conditions of food processing.

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113 See id.


116 MARK SULLIVAN, *OUR TIMES* 222 (Scribner 1996).

117 SINCLAIR, supra note 115.

2. **1906 Pure Food and Drug Act**

As a result of the public furor following publication of *The Jungle*, on June 30, 1906, President Theodore Roosevelt signed into law both the Pure Food and Drug Act\(^{119}\) and the Meat Inspection Act,\(^{120}\) thus commencing the modern era of U.S. food regulation. While the primary purpose of the Act was to prevent the use of potentially harmful constituents, a secondary objective was to protect the public from the possibility that valuable ingredients would be watered down or left out of basic foods in favor of cheaper substitutes.\(^{121}\) “Upon the passage of the 1906 Act, the Government began a vigorous attack upon economic adulteration in both criminal and civil cases. Convictions were secured in numerous criminal cases.”\(^{122}\) Although the Act appeared to adequately address blatant cases of economic adulteration, the concern became focused on imitation products.\(^{123}\) The concern was that with advancements in food technology, manufacturers could produce new products that resembled, but were not identical to,

\(^{119}\) Pure Food and Drugs Act, ch. 3915, § 6, 34 Stat. 768 (1906) (repealed 1938).


\(^{122}\) Wesley E. Forte, *The Food and Drug Administration and the Economic Adulteration of Foods*, 41 IND. L.J. 346, 352 (1965); see, e.g., Union Dairy Co. v. United States, 250 Fed. 231 (7th Cir. 1918) (milk diluted by water); Frank v. United States, 192 Fed. 864 (6th Cir. 1911) (pepper diluted by corn); United States v. Frank, 189 Fed. 195 (S.D. Ohio 1911) (lemon extract diluted by alcohol and water); United States v. South Hero Creamery Ass’n, White & Gates 1142 (D. Vt. 1925) (butter with less than 80 per cent milk-fat); United States v. Atlantic Macaroni Co., White & Gates 793 (E.D.N.Y. 1917) (macaroni dyed yellow to conceal inferiority); United States v. German American Specialty Co., White & Gates 459 (S.D.N.Y. 1913) (eggs diluted by skim milk).

traditional foods. However, absent formal standards, courts held that fabricated food products were not adulterated, but were a pure and distinct separate food product. The government suffered a number of defeats. Especially problematic was the Eighth Circuit’s decision in *United States v. 10 Cases, More or Less, Bred Spred*, that found that “Bred Spred” was not an adulterated version of jam, even though it closely resembled jam and had less than half as much fruit, because there was no authoritative standard for comparing “Bred Spred” with jam and no misleading statements on the “Bred Spred” labeling.


Partly in response to these perceived shortcomings, in 1938 Congress passed the Federal Food and Drug Act (FD&C Act), which has since served as the statutory basis for food regulation in the U.S. Safety and health problems were to be regulated through the adulteration provisions of section 402 — section 402(b) provides the FDA clear authority to act in cases involving economic adulteration. Under this section, a food is deemed adulterated:

1. If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or
2. If any substance has been substituted wholly or in part therefore; or
3. If damage or inferiority has been concealed in any manner; or

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124 *See id.*


126 Forte, *supra* note 122, at 353.

127 *United States v. Ten Cases Bred Spred*, 49 F.2d 87 (8th Cir. 1931).


129 FDCA § 402(b).
(4) If any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or greater value than it is.\footnote{Id., 21 U.S.C. § 342(b).}

The FDA has authority to act even if the economic adulteration poses no known risk to public health.

Another important provision of the FD&C Act that was designed to avoid the upshot of the \textit{Bred Spred} case – that labeling requirements could combat economic adulteration – is section 401, which gives FDA broad authority to establish identity standards for foods: “Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers he shall promulgate regulations fixing and establishing for any food, under its common or usual name as far as practicable, a reasonable definition and standard of identity . . . .”\footnote{FDCA § 401, 21 U.S.C. § 341.} Standards of identity are used as a "yardstick" by which to measure economic adulteration.\footnote{See Merrill, supra note 121, at 563.} A FDA standard of identity defines the composition of a food and may prescribe a method of production or formulation.\footnote{Id. at 563.} The resulting standard closely resembles a recipe.\footnote{See id.} As part of the standard, the FDA assigns a name under which all conforming products shall be sold.\footnote{See id.} “Once a food has been standardized, no product that fails to meet the compositional requirements of the standard may be marketed under the name the FDA has appropriated.”\footnote{Id.}

\footnote{Id., 21 U.S.C. § 342(b).}
\footnote{FDCA § 401, 21 U.S.C. § 341.}
\footnote{See Merrill, supra note 121, at 563.}
\footnote{Id. at 563.}
\footnote{See id.}
\footnote{See id.}
\footnote{Id.}
The controlling provision of the FD&C Act is section 403(g), which states that a food shall be deemed misbranded:

[i]f it purports to be or is represented as a food for which a definition and standard of identity has been prescribed . . . unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard . . . . Accordingly, a product that "purports to be or is represented as" a standardized food either must meet the standard or it may not be sold.\textsuperscript{137}

The FDA moved quickly to implement and enforce food identity standards. From 1938 through the 1960s, the FDA promulgated highly detailed "recipe" standards of food identity and vigorously enforced standards of identity during this period.\textsuperscript{138} By 1972, there were 248 standardized foods.\textsuperscript{139} In the 1970s, however, standards began to lose favor with the FDA, as the rapid increase in the variety of food products available in the marketplace caused the standards of identity to be viewed as unwieldy.\textsuperscript{140} In the recent book, \textit{Squeezed}, Alissa Hamilton, by chronicling the development of standards for orange juice in the 1960s, demonstrates that standards of identity are expensive, convoluted and political.\textsuperscript{141} Additionally, standards of identity lost their enforcement power when the FDA moved to a greater reliance on information labeling to prevent consumer deception of identity and on to “hard-core credence issues” such as nutrition and safety.\textsuperscript{142} Vice-President Al Gore’s shock at learning that the FDA set forth precise

\textsuperscript{137} FDCA § 403(g), 21 U.S.C. § 343(g).

\textsuperscript{138} See Merrill, supra note 121, at 566.

\textsuperscript{139} See id.

\textsuperscript{140} Takaki, supra note 125, at 680.

\textsuperscript{141} See ALISSA HAMILTON, SQUEEZED: WHAT YOU DON’T KNOW ABOUT ORANGE JUICE (Yale University Press 2009).

standards for the shapes in which canned green beans could be sold spurred a 1995 advance notice of proposed rulemaking to solicit comments on the viability of food standards.\footnote{See Stuart M. Pape, Food Standards – Are They Obsolete?, Prepared Foods 33 (June 1996), http://findarticles.com/p/articles/mi_m3289/is_n7_v165/ai_18515392/} Although the value of standards has been deprecated, one commentator notes that “amidst all the ridicule, [food standards] are serious issues of food policy with enormous implications for both domestic and international trade in foodstuffs.”\footnote{Id.} As will be seen later in this article, the use of standards of identity by states has recently gained favor as a way to prevent economic adulteration, but on a federal level, there is little enthusiasm for the endeavor.

A leading case that further limited the scope of the FD&C Act is the 1951 decision in United States v. 88 Cases, More of Less, Containing Bireley's Orange Beverage.\footnote{See 187 F.2d 967, 971 (3d Cir. 1951).} The Third Circuit court found that even though "Bireleys" was an orange drink containing 6% orange juice, 2% lemon juice, 87% water and artificial coloring, it was not deleterious.\footnote{See id. at 974.} The government contended that since yellow coal tar dye had been added to change the beverage's naturally unattractive appearance into a rich orange color, the drink had been made to "appear better or of greater value than it [was]."\footnote{Id. at 969.} The court conceded that this was literally true, but denied that a product can "appear better than it is" within the meaning of the FD&C Act unless the food is made to appear to be some defined superior product.\footnote{Id. at 974.} Critics charged that this decision returned the law of economic adulteration back to the state it was under the 1906 case and the

\footnote{See Stuart M. Pape, Food Standards – Are They Obsolete?, Prepared Foods 33 (June 1996), http://findarticles.com/p/articles/mi_m3289/is_n7_v165/ai_18515392/}
Bred Spred case. \footnote{See Economic Adulteration-Determination of Whether a Food Has Been Made to “Appear Better or of Greater Value Than it is, 100 U. PA. L. REV. 139 (1951).} Although Bireley’s is not relevant to indisputable fraud, as in the present case of 100% pomegranate concentrate where there is a clearly defined superior standard, it is illustrative of the narrowing of the application of section 402 to accommodate developing food technology.

4. **Lack of Enforcement**

Some scholars believe section 402(b) is no longer enforced – except for outright fraud – because enforcement is incompatible with modern food technology. This argument is made in the 3rd Edition of *Food and Drug Law* as follows:

> Applied literally, the economic adulteration provisions of the FD&C Act would render most modern food technology problematic. Many functional ingredients – color additives, preservatives, emulsifiers – are intended to improve the appearance of the product and thus could be challenged as making food appear ‘better than it is.’ Food producers would claim that these ingredients in fact improve the food and only make it appear to be as good as it genuinely is. Without purporting to resolve this debate, FDA has virtually abandoned enforcement of section 402(b) except in cases of outright fraud, which are rare. The agency has embraced though never publicized, the philosophy that, notwithstanding the proper legal interpretation of the statute, informative labeling can cure ‘economic adulteration.’ \footnote{Peter Barton Hutt, Richard A. Merrill & Lewis A. Grossman, Food and Drug Law: Cases and Materials 159 (Foundation Press 2007, 3rd ed.) (emphasis added).}

The irony is that while technology has led to innovative, novel food products that would be stifled by the economic provisions of the FD&C Act, technology also permits unethical parties to employ sophisticated adulteration procedures for profit. \footnote{R. Shapiro, The Double-Edged Sword of Technological Advancement: Food Authenticity and Economic Adulteration, Cereal Foods World (2000).}
In cases of outright fraud, there are a few well-known precedents where the FDA exercised its statutory responsibility to enforce against the perpetuators. Enforcement led to a $100,000 fine and five-year prison sentence for the former president and chief-executive officer of an orange juice company that put more than forty million gallons of adulterated orange juice on the U.S. market over eleven years.\(^\text{152}\) Fines and forfeitures totaling $120,000 were slapped on a seafood company and two of its principals for adding water to scallops to increase their weight and thus net profit since scallops are priced according to weight.\(^\text{153}\) Fines of $20,000 each and prison terms of 19 months and 30 months were issued for two Mississippi brothers for adulterating pure honey and pure maple, can and sorghum syrups that were sold in old-fashion tins at farmers’ markets and produce stands around the country.\(^\text{154}\) A $2.18 million fine was issued for Beech-Nut Nutrition Corporation – an established baby food manufacturer – for selling a product labeled “100 percent” apple juice but which actually contained only sugar, water and flavoring.\(^\text{155}\) Notwithstanding the sizeable fine issued against Beech-Nut Nutrition Corporation, juice adulteration in the U.S. proliferated in the early 1990s, when it was estimated that 10% of fruit juice sold in the U.S. was not all juice.\(^\text{156}\) David A. Kessler, then commissioner of the FDA, expressed determination at the time to criminally prosecute adulteration cases. He noted that “these are serious prosecutions . . . [p]eople are going to jail.”\(^\text{157}\)

\(^\text{152}\) See Paul Kurtzeweil, *Fake Food Fight*, FDA Consumer (March-April 1999).

\(^\text{153}\) See *id.*

\(^\text{154}\) See *id.*

\(^\text{155}\) See *id.*


\(^\text{157}\) *Id.*
enthusiasm of Dr. Kessler, however, was the FDA’s enduring problem of inadequate resources and an “institutional tradition” of putting a low priority on prosecuting cases of economic adulteration.158

The FDA’s reluctance to vigorously enforce against economic adulteration is not surprising; FDA enforcement decisions are often guided more by exiguous circumstances than by public policy. With limited resources, the agency struggles to enforce its statutory mandates, including that of stopping economic adulteration. FDA has been aptly described as having become a “paradigmatic example of the ‘hallow government’ syndrome – an agency with expanded responsibilities, stagnant resources, and the consequent inability to implement or enforce its statutory mandates.”159 The FDA’s budget has stayed roughly the same for more than a decade, despite FDA facing many new and complex problems.160

In addition to resource limitations, the reluctance by the FDA to enforce against economic adulteration may also be due to a change in focus over time that diminished its resolve to address economic matters. The FDA’s original regulatory focus on fraud in the marketplace expanded into mechanisms to protect consumers against unsafe food.161 The FDA later adapted to the science of nutrition and assumed a role in protecting the nutritional integrity of the food supply.162 This shift away from fraud, combined with the FDA’s resource constraints, has

158 See id.

159 Peter Barton Hutt, The State of Science at the Food and Drug Administration, 60 ADMIN. L. REV. 431, 432 (2008).


162 Id.
relegated economic adulteration to low priority status, behind safety and nutrition.\footnote{See PETER BARTON HUTT AND RICHARD A. MERRILL, FOOD AND DRUG LAW CASES AND MATERIALS, 1056-57 (Foundation Press 1991, 2nd ed.).} For example, in a letter to the National Milk Producers Federation over the issue of “imitation” labeling, the agency stated that “[o]ur high priorities are health hazards, filth, and nutrition. Our lowest priorities are food economics and food standards. Thus we expect no actions in the near future concerning cheese substitute products indicated in your letters.”\footnote{Id. at 1057.} The assumption of this relegation of fraud as a low priority is that economic adulteration does not pose significant health risks.\footnote{Jeneen Interlandi, The Fake-Food Detectives, Newsweek (Feb. 8, 2010), available at http://www.newsweek.com/id/233253.} 100% pomegranate juice exemplifies this assumption. The court in \textit{Purely Juice} determined that as early as 2006, “it was widely known in the super premium juice industry that there were serious issues of adulteration with pomegranate juice concentrate originating from outside the United States.”\footnote{POM Wonderful LLC v. Purely Juice, Inc., No. 07-02633, 2008 WL 4222045, at *5 (C.D. Cal. July 17, 2008), aff’d, No. 08-56375, 2009 WL 5184233 (9th Cir. Dec. 28, 2009).} The same evidence of fraud from seven certified laboratories that was found to be persuasive to the California District Court in \textit{Purely Juice} was provided to the FDA, along with the request that the agency take “prompt, forceful and visible regulatory action” against companies selling adulterated product.\footnote{See Letter from law firm of Hogan & Hartson to Joseph R. Baca, Director, Office of Compliance, CFSAN, FDA (April 17, 2007) (on file with author). See, e.g., Krueger Food Laboratories, Inc., Certificate of Analysis (Apr. 2, 2007) (on file with author). See also \textit{Purely Juice}, 2008 WL 4222045 at *4 (describing tests conducted by Krueger on Purely Juice’s 100% pomegranate juice and the results).} In January 2008, the FDA notified complainants that due to a lack of resources both to investigate and develop sufficient sophisticated methodology to analyze the adulteration, it was unwilling to commit resources to
investigate the economic adulteration of 100% pomegranate juice.\textsuperscript{168} In the words of a FDA food-safety officer, “[i]n terms of priorities, [food fraud] often ranks at the bottom of the list.”\textsuperscript{169} The danger with this assumption is that it fails to appreciate the emerging interconnection in the new global food trade system between economic adulteration, especially high-premium healthy products like 100% pomegranate juice, and safety and nutrition.

\textsuperscript{168} See Baca Letter, \textit{supra} note 167. Complainants will not find help from courts to compel action by the FDA, as the U.S. Supreme Court in \textit{Heckler v. Chaney} determined that decisions by the FDA not to take enforcement actions are presumptively unreviewable, as such actions are “committed to agency discretion by law” under section 701(a)(2) of the Administrative Procedure Act. \textit{Heckler v. Chaney}, 470 U.S. 821 (1985).

\textsuperscript{169} Jeneen Interlandi, \textit{supra} note 165.
C. Globalization and the FDA’s Budding Interest

The melamine public-health disaster in China jolted the food industry and government agencies, including the FDA, into at least an introspective mode concerning economically-motivated adulteration. There is a growing recognition that globalization means that economic adulteration cases of “outright fraud” are no longer rare in a global food system that is growing more dependent every day on the importation of food and that there are potentially serious food-safety consequences from unchecked adulteration.\textsuperscript{170}

1. FDA Public Hearing

Notwithstanding the general disinclination by the FDA towards enforcement against economic adulteration, on April 6, 2009, the FDA announced a Public Meeting pertaining to economically-motivated adulteration.\textsuperscript{171} FDA called the meeting “to stimulate and focus discussion about ways in which the food, drug, medical device, and cosmetic industries, regulatory agencies, and other parties can better predict and prevent [economically-motivated-adulteration] with a focus on situations that pose the greatest public health risk.”\textsuperscript{172} The specific purpose “of the meeting was to stimulate discussion on how industry can better predict and prevent economically motivated adulteration of food.”\textsuperscript{173} The FDA noted that “[d]espite longstanding FDA requirements to assure the safety of registered products, such as requirements

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\textsuperscript{170} See AT Kearney, supra note 2, at 4.

\textsuperscript{171} See FDA Note of Public Meeting, supra note 14.

\textsuperscript{172} Id.

\textsuperscript{173} Id. at 15497.
for the use of ingredients of known identity and quality in drugs, economically motivated
adulteration remains a public health threat.”

For purposes of the meeting, FDA proposed that economically motivated adulteration be
defined as “the fraudulent, intentional substitution or addition of a substance in a product for the
purpose of increasing the apparent value of the product or reducing the cost of its production,
i.e., for economic gain.” The FDA further clarified that this would include dilution of
products with an already present substance, “to the extent that such dilution poses a known or
possible health risk to consumers . . . as well as the addition or substitution of substances in order
to mask dilution.”

The FDA’s principle concern at the meeting on May 1, 2009 was the affect of the
importation of foods on economic adulteration. Based on presentations at a recent FDA public
meeting on economic adulteration, the proliferation of imported food products subject to
economic adulteration include honey, oils, spices, supplements, wheat gluten, seafood, pet food,
and superfruit juices. Much of this product is imported from developing countries, who
themselves have reported in the last year a significant increase in the amount of economic
adulteration of food product.

Three of the four examples of economically-motivated adulteration provided by the
FDA’s Federal Register notice announcing the meeting involve mainland Chinese products, and

174 Id. at 15498.
175 Id.
176 Id.
177 See generally FDA Public Meeting, supra note 14.
178 See id. (statement of Shaun Kennedy).
the fourth example is partially linked to mainland Chinese manufacturers as well.\textsuperscript{179} The first of these incidents include the contamination in 2007 of pet food containing ingredients labeled as wheat gluten and rice protein concentrate that included melamine and melamine-related compounds.\textsuperscript{180} Melamine was allegedly added to the pet food to boost its protein content.\textsuperscript{181} The other two incidents involve the contamination in 2008 of heparin products used in paediatric dialysis patients with a heparin-like molecule known as oversulfated chondroitin sulphate that was manufactured in the mainland, and the contamination in 2008 of milk-based infant formula with melamine added to increase measured nitrogen levels and thereby inflate the apparent protein content.\textsuperscript{182} The fourth example involves the adulteration of toothpaste, cough syrup, and other drugs with diethylene glycol which is used to replace glycerine in those products.\textsuperscript{183}

The FDA’s opening comments at the meeting, made by Dr. Randall Lutter, address the changing paradigm for economic adulteration that results from globalization. Dr. Lutter stated that “[t]he reason this problem has resurged is largely because of globalization. That’s the new challenge that we face.”\textsuperscript{184} He further noted that “[p]rotection at the border is intrinsically more challenging. Inspections are most costly overseas, equivalent state regulatory agencies do not exist and other information is more scarce.”\textsuperscript{185} He concluded by stating “[s]o our strategy for identifying the next melamine, if you will . . . is that large-scale economically-motivated

\textsuperscript{179} See id.

\textsuperscript{180} See id.

\textsuperscript{181} See id.

\textsuperscript{182} See id.

\textsuperscript{183} See id.

\textsuperscript{184} See id. at 4.

\textsuperscript{185} Id.
contamination is likely where people can make money. And to put it more specifically, the expected reward to somebody from this illegal activity is – exceeds expected costs.”

During the public meeting, the FDA received no shortage of suggestions on how to better prevent, detect, and address instances of economic adulteration. Suggestions included increased educational outreach, improved enforcement at the borders, more prosecutions, and establishing a greater presence abroad. A number of industry representatives also expressed the view that FDA should broaden its working definition of economic adulteration to address situations that do not necessarily pose a public health risk, but that nonetheless threaten to undermine product integrity in certain industries. The suggestion that received the most attention was for the FDA to step up its enforcement activity.

2. GMA Report

In early 2010, following the FDA public hearing, the Grocery Manufacturer’s Association (GMA), a trade group that represents the food, beverage, and consumer products industry, issued a lengthy report about the increasingly significant problem of food-product fraud in the global marketplace, including economic adulteration and counterfeiting. Consistent with FDA statements, the report characterizes the melamine incident in China as the trigger point which proved that economic adulteration has serious global consequences. The report

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186 Id. at 4-5.
187 See generally id.
188 See id.
189 See id.
190 ATKearney, supra note 170 at 1 (counterfeiting is defined as the unauthorized representation of a registered trademark carried on goods similar to goods for which the trademark is registered, with a view to deceiving the purchaser into believing that he or she is buying the original goods). Id.
191 Id. at 1.
accounts for the spike in global economic adulteration in part by noting that technology has allowed cheaters to become more sophisticated.\textsuperscript{192} For example, in the melamine incident, the guilty parties used their knowledge of the “value” ingredient protein — and the indirect nitrogen-based testing method used to measure it — to mask and enhance the naturally occurring protein levels in milk products and cheat the test methods.\textsuperscript{193} Another problem cited by the report is the culture of acceptance of cheating, especially “[i]n markets where there exists severe economic tension, weak regulations and poor legal frameworks . . . .“\textsuperscript{194} The report calls on governments “to more effectively execute existing laws and regulations and to deter fraud and protect consumers and increase penalties for violators.”\textsuperscript{195} Given GMA’s role as an industry association, the report predictably encourages governments to coordinate with all stakeholders throughout the food supply chain and collaborate with trading partners to reduce fraudulent activity.\textsuperscript{196} An interesting idea in the report is for governments to “consider establishing a center of expertise for food fraud similar to efforts on food safety and defense”\textsuperscript{197}

IV. Defining the Appropriate Role of Government Enforcement Against Economic Adulteration

The FDA views itself as a “scientifically oriented law enforcement agency” with a mission to protect consumers through judicious enforcement of various laws entrusted to its

\textsuperscript{192} Id. at 5.
\textsuperscript{193} Id. at 5.
\textsuperscript{194} Id. at 5.
\textsuperscript{195} Id. at 17.
\textsuperscript{196} Id.
\textsuperscript{197} Id.
administration. To determine what constitutes “judicious enforcement” against the type of economic adulteration that has emerged in the global food trade system – such as in the case of 100% pomegranate juice – it is useful first to inventory and assess the enforcement tools available to FDA, and second to frame a cost-benefit analysis that while often associated with the promotion of economic efficiency is best understood as a way of ensuring “better priority setting and of overcoming predictable obstacles to desirable regulation . . .”

A. FDA Enforcement Tools at the Border

Imported food fraud presents a special challenge for enforcement because a nation’s food regulatory jurisdiction ends at its national border. This limits the regulator’s ability to induce a foreign supplier’s compliance with domestic food standards using traditional avenues of law and regulation backed by civil, criminal, and administrative penalties. International agreements that comprise rules to govern international trade in food goods, including the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and World Trade Organization Agreement on Technical Barriers to Trade (TBT Agreement), are historically slanted toward removing trade barriers rather than assessing accountability. Thus, the safety and integrity of imported food depends on the importing country’s regulations and enforcement activity.

1. Section 801, FD&C Act: Import Alerts

FDA’s authority over imported food is derived from section 801 of the FD&C Act. The authority over imported food is derived from section 801 of the FD&C Act. Section 801(a) prescribes that a food may be refused entry into the United States if it appears to be manufactured, processed, or packed under unsanitary conditions or if it is adulterated or misbranded. The basic enforcement tool used by FDA in connection with imported food is the automatic detention of goods through what are known as import alerts. This administrative remedy allows for a specific food article to be detained without physical examination. Import alerts are guidance documents that inform FDA field personnel that the FDA has sufficient evidence about a product, producer, shipper, or importer to determine that the food article is unsuitable for import. Examples of import alerts for adulterated product include an alert in August 2007 that detained farm-raised catfish, basa, shrimp, dace, and eel products from China after the discovery of unapproved drug residues and food additives. In 2008, FDA issued import alerts for vegetable protein and milk products tainted with melamine from


202 See FDCA § 801(a), 21 U.S.C. § 381(a).

203 See FDA REGULATORY PROCEDURES MANUAL chs. 9-21 (Mar. 2009).

204 See id.

205 Id.

China.\textsuperscript{207} There have even been FDA import alerts for economic adulteration unrelated to safety concerns. In the 1990s an import alert that still remains in effect was issued for apple juice and apple juice concentrate that contained an undeclared sweetener that rendered the products both economically adulterated and misbranded.\textsuperscript{208} Another import alert unrelated to safety concerns was issued by the FDA in for morel mushrooms, due both to microbial contamination and substitution of less valuable mushrooms for a portion of the morels.\textsuperscript{209} Finally, another import alert covers numerous products and importers due to violation of the Nutrition Labeling and Education Act of 1990, which nutrition labeling and ingredient declaration requirements that are unrelated to food safety.\textsuperscript{210}

The lack of resources limits the application of import alerts. While the number of food imports has increased exponentially, the number of import inspectors has remained stagnant.\textsuperscript{211} Only 1.3\% of imported food is inspected by FDA.\textsuperscript{212} The FDA information systems focused on imports are old and out of date, making it difficult to interact directly with the Customs Border

\textsuperscript{207} See Import Alert #99-29, Detention without Physical Examination of All Vegetable Protein Products from China for Animal or Human Food Use Due to the Presence of Melamine and/or Melamine Analogs (2008), \url{http://www.accessdata.fda.gov/ImportAlerts/ora_import_ia9929.html}; See also Import Alert #99-30, Detention without Physical Examination of All Milk Products, Milk Derived Ingredients and Finished Food Products Containing Milk from China Due to the Presence of Melamine and/or Melamine Analogs (2008), \url{http://www.accessdata.fda.gov/cms_ia/importalert_54.html}.

\textsuperscript{208} See Import Alert #20-02, Detention Without Physical Examination of Apple Juice and Apple Juice Concentration Containing an Undeclared Sweetner (2009), \url{http://www.accessdata.fda.gov/cms_ia/importalert_54.html}.

\textsuperscript{209} See Import Alert #99-20, Detention Without Physical Examination of Morel Mushrooms Due to Adulteration and Substitution (2009), \url{http://www.accessdata.fda.gov/cms_ia/importalert_80.html}.

\textsuperscript{210} See Import Alert #99-20, Detention Without Physical Examination of Imported Food Products Due to NLEA Violations (2010), \url{http://www.accessdata.fda.gov/cms_ia/importalert_264.html}.

\textsuperscript{211} Hubbard, \textit{supra} note 160.

\textsuperscript{212} See Bridges, \textit{supra} note 3.
Patrol.\textsuperscript{213} Given these resource constraints, there should be no surprise that after the import alerts were issued for Chinese seafood, at least one million pounds of suspect Chinese seafood made it through without being stopped and tested, thereby landing on store shelves and dinner plates.\textsuperscript{214}

2. Bioterrorism Act: Notice

Another useful tool for the FDA for import control of food product is the Public Health Security and Bioterrorism Preparedness and Response Act (Bioterrorism Act), enacted by Congress in 2002.\textsuperscript{215} Under the Bioterrorism Act and the Final Rule issued on November 7, 2008 (effective May 6, 2009), importers are required to submit to FDA “prior notice of food, including animal feed, that is imported or offered for import into the United States.”\textsuperscript{216} The FDA receives 33,400 prior notice submissions each business day.\textsuperscript{217} Although the Bioterrorism Act does not stop the importation of economically-motivated adulterated food product, prior notice allows the FDA to work closely with the Customs Boarder Patrol to identify and trace back imports of adulterated product that threaten the food supply.\textsuperscript{218}

\textsuperscript{213} Id.


\textsuperscript{217} Acheson, \textit{supra} note 201.

\textsuperscript{218} See id.
3. The Food Safety Enhancement Act of 2009

A positive development in the overall strengthening of the FDA’s border enforcement activity is the Food Safety Enhancement Act of 2009, known as H.R. 2749, which was passed on July 30, 2009 by the House of Representatives.219 The purpose of the Act is “[t]o amend the Federal Food, Drug, and Cosmetic Act to improve the safety of food in the global market, and for other purposes.”220 The Act remains to be voted in the Senate. The Act enhances the FDA’s enforcement oversight on imported foods. The Act requires facilities operating within the U.S. or importing food to the U.S. to implement safety plans that identify and protect against food hazards.221 Each domestic or foreign owner or operator is required to implement a written food safety plan describing its hazard analysis and preventive controls before the product enters interstate commerce.222 Records must be maintained to document steps to implement, correct, monitor and revise the safety plan.223 As an additional layer of protection, the FDA can require the originating country’s government or qualified certifying entities to certify that the imported food has met all U.S. food safety requirements.224 Third party certifying entities must meet strict requirements to protect against conflicts of interest with the firm seeking certification.225 The Act permits the FDA to develop voluntary security guidelines for imported foods in order to


221 See id. at § 102.

222 See id.

223 See id.

224 See generally id. at § 109.

225 See id.
expedite the importation process. In establishing who qualifies for the program, FDA would consider the personnel of the importers, security of the supply chain, preventive controls and vendor and supplier information. Finally, the Act authorizes the Secretary of Agriculture to issue propose regulations establishing new food traceability requirements for domestic and imported food. Prior to issuance, FDA would be required to conduct an information gathering process to determine the feasibility and cost/benefit of the system. Any system must allow the Secretary to conduct the traceback within two business days. While it is unclear to what extent these changes would bear on economic adulteration of imported food product, arguably more attention would be focused on the overall compliance of imports.

B. “Standards” Activity

Standards of identity to stop the import of economically adulterated food product have been employed recently for three premium food products: honey or “pure” honey, extra virgin olive oil, and 100% pomegranate juice.

1. Honey

In the sweetener industry, honey is a prime target for economic adulteration – a problem that has been exasperated by the increase of foreign imports. In 2006, five major honey producers and processors asked the FDA to establish a standard of identity for honey. Two years later the FDA responded that, due to other pressing matters, it would not be able to review the

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226 See id. at § 113.
227 See id.
228 See id. at § 107.
229 See id.
230 See id.
231 Fairchild, supra note 60, at 1.
petition. Florida then instituted a state standard of identity that prohibits any additives, chemicals, or adulterants in honey produced, processed, or sold in Florida. In 2009, Congress stepped in, and as recorded in the June 23, 2009, House Agriculture Appropriations Committee Report accompanying the 2010 Agriculture Appropriations bill, the Committee references the problem of economically-motivated adulterated honey entering the U.S. market and directs FDA as follows:

Honey.—The Committee recognizes that honey is produced in the United States, traded internationally and consumed as both a packaged food and as a food ingredient. However, there have been instances where manufacturers have been marketing products illegally as ‘‘honey’’ or ‘‘pure honey’’ that contained other ingredients. The Committee believes that guidance about the composition and labeling of honey is needed to protect consumers and the domestic honey industry from misbranded honey and honey-derived products that are currently entering the U.S. market. The Committee directs FDA to remind manufacturers of honey about the misbranding and adulteration provisions of the Federal Food Drug and Cosmetic Act. It is the Committee’s understanding that FDA intends to respond to the pending citizen petition proposing a standard of identity for honey, and the Committee expects the agency to do so.

Similarly, the July 7, 2009, Senate Agriculture Appropriations Committee report accompanying the companion Senate bill included the following directive:

Standards of Identity.—The Committee recognizes that honey is produced in the United States, traded internationally and consumed as both a packaged food and as a food ingredient, and believes FDA needs to work to prevent misbranded honey and honey derived products from entering the U.S. market. The Committee is aware that the FDA has been in receipt of a proposed standard of identity for honey for 3 years, and directs FDA

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233 Id.

to respond to this proposal and, if deemed appropriate, begin working toward a U.S. standard of identity for honey.\textsuperscript{235}

Thus, it appears that Congress is willing to direct an otherwise resistive FDA to take enforcement action for economic adulteration involving the importation of adulterated food even where no safety risk is present.

2. **Olive Oil**

Like pomegranates, olive oil has a long history rich in lore, used for centuries for medicine and religious rituals.\(^ {236}\) In recent years, American per capita olive oil consumption has exploded, with the annual per capita olive oil consumption in the U.S. having increased over 650% since 1980. Much of this demand has been generated by olive oil becoming over recent years a gourmet must-have item, and by the higher-graded olive oil being touted for its heart-health properties and taste.\(^ {237}\) The higher-grade extra virgin oil is one of the most frequently economically adulterated food products, including in Europe, where fraud was so bad in the late 1990s that the European Union’s anti-fraud office established an olive-oil task force.\(^ {238}\) According to one investigator, “[p]rofits were comparable to cocaine trafficking, with none of the risks. . . .”\(^ {239}\) High-end olive oil is expensive to produce and fraudulent extra virgin olive oil was priced substantially less than the pure product.\(^ {240}\)

Proponents for preserving the integrity and health benefits of the extra virgin oil have petitioned the FDA for a standard of identity based on a standard set by the International Olive

\(^{236}\) See José Mataix & Javier Barbancho, Olive Oil & Health 26 (2006).


\(^{239}\) Id.

\(^{240}\) Id. Low-grade olive oil housed in tins labeled as extra virgin were found to be mostly soybean oil mixed with low grade olive-pomace oil.
Council (IOC).

This standard two-fold: first, an objective chemical test considers the level of fats and oils present in the olive oil; second, a subjective organoleptic test (i.e., taste, smell and appearance) checks the purity of the olive oil product. Oil qualifying as extra virgin must pass both of these tests. Given the FDA’s reluctance to act on petitions for standards of identity, there is not much enthusiasm for the FDA moving quickly on a petition. There is also a petition to the USDA for a voluntary standard that appears also to be languishing.

The federal government’s delay in setting standards of identity has shifted enforcement activity to the state level. Connecticut began testing for extra virgin oil in 2007, and in November 2008 it became the first state to adopt a standard of identity that mirrors standards developed by IOC. State officials were concerned about the safety of economically adulterated olive oil, especially the prospects of allergen problems. Following Connecticut’s example, California has created standards for olive oil, including extra virgin oil, which follow the IOC standards. Other states are also considering adopting similar standards for olive oil.

241 See NAOOA Mid-Year Meeting Minutes and Presentations (Posted February 7, 2008), http://www.mytradeassociation.org/cgi-bin/moxiebin/bm_tools.cgi?print=82;=2;=2;=site=4.


243 See NAOOA, supra note 241.

244 See id. See also AMS, Notice for Proposed United States Standards for Grades of Olive Oil and Olive-Pomace Oil, 73 Fed. Reg. 31426 (June 2, 2008).


248 Associated Press, supra note 246.
3. **100% Pomegranate Juice**

The proponents of a California 100% pomegranate juice bill hope to mirror the success of the state standards established for extra virgin oil. Efforts to stop the economic fraud of 100% pomegranate juice are now in the form of a proposed bill that is working its way through the California legislative process that would establish a standard of identity for the pure, 100% pomegranate juice.\(^{249}\) The stated purpose of the bill is to address issues of economic adulteration of pomegranate juice originating from outside the United States.\(^{250}\) The standard will likely be based on authentication standards that are developed in what is referred to as the recently published *International Multidimensional Authenticity Specification (IMAS) Algorithm for Detection of Commercial Pomegranate Juice Adulteration.*\(^{251}\) The IMAS algorithm was developed through consideration of existing databases and comprehensive chemical characterization of 45 commercial juice samples from twenty-three different manufacturers in the United States.\(^{252}\) In addition to analysis of commercial juice samples obtained in the United States, data from other analyses of pomegranate juice and fruits including samples from Iran, Turkey, Azerbaijan, Syria, India, and China were considered in developing this protocol.\(^{253}\) The profile generated from these analyses combined with information from existing databases and

\(^{249}\) See SB 190, 2009 (Cal. 2009).


\(^{251}\) See Krueger, supra note 15.

\(^{252}\) See id. at E.

\(^{253}\) See id. at A.
published literature has been integrated into a validated IMAS for pomegranate juices which can be utilized to detect adulteration of 100% pomegranate juice.\textsuperscript{254}

Notwithstanding these developments and a recent, general recognition of the effects of globalization on economic adulteration, enforcement remains limited. Notwithstanding examples of a few exceptions, the general rule is that for the FDA to initiate an import alert against adulterated imported food product, the contamination must first ripen into an immediate, discernable food-safety risk. While this recalcitrance may reflect the FDA’s traditional method of doing business, it does raise the issue of whether the costs of unchecked economic adulteration in the emergent global food trading system are fully understood and sufficiently weighed.

C. Measuring the Costs of Failure to Enforce

Effective “cost-benefit balancing” that is “enshrined in the formal law of the executive branch” requires that a deliberative process be engaged to know the “real costs.”\textsuperscript{255} A problem with the FDA’s current mind set in assessing the costs of economic adulteration is that a single incident is not likely going to amount to an immediate threat to food-safety. The importance of safe food is obvious. There is little dispute that significant resources should be devoted to food safety regulation. Addressing adulteration problems in isolation, basing enforcement activity exclusively on the immediate food-safety impact, is short-sighted in a global regulatory system because the “real” costs are not factored into the deliberative process. Indeed, globalization of food distribution not only introduces additional costs, but changes the cost-assessment paradigm.

\textsuperscript{254} See generally id.

\textsuperscript{255} \textit{Cass R. Sunstein, Risk and Reason} 6-7 (Cambridge University Press 2002).
for imported food. Costs should be assessed in a coherent, cognitive and holistic approach.\textsuperscript{256} Such an approach accounts both for the growth of economic adulteration due to globalization and the full range of public-health, governance, and economic and social costs of non-enforcement.\textsuperscript{257} Below is a sampling of the costs of unchecked economic adulteration of imported food product. These costs are not exhaustive, but provide a framework for further analysis and consideration in risk assessment.

1. **Public-Health Costs**

   Non-enforcement of economic adulteration of imported food product increases food safety risks. As noted in the melamine disaster, economic adulteration poses the risk of unintended consequences, such as olive oil adulterated with peanut oil being unwittingly served to someone with a peanut allergy, or someone eating a mislabeled fish of which they are allergic.\textsuperscript{258} Former FDA Commissioner David A. Kessler observed that “[i]n most cases of adulteration, it turns out to be just economic and nobody gets hurt – but there is always that potential.”\textsuperscript{259} It stands to reason that to continue to marginalize economic adulteration as a low priority – meaning no enforcement – the FDA not only condones, but unwittingly enables and even encourages additional unscrupulous manufacturers to cheat in order to increase their profits. Simply put, waiting for a melamine-type tragedy to strike before initiating enforcement increases the chances that such a tragedy will occur. This is precisely what happened in the two melamine adulteration cases in China, where manufacturers added the chemical to increase measured

\textsuperscript{256} See generally id. at 1071-722 (assessing a separate evaluation and incoherence in cost-benefit analysis).

\textsuperscript{257} See id. at 8-9

\textsuperscript{258} Interlandi, supra note 165.

\textsuperscript{259} Henriques, supra note 156.
nitrogen levels in order to reduce costs and inflate the protein content.\textsuperscript{260} It is naïve to hope that these same cheaters will be concerned about safety while adulterating a product for profit. The benefit of deterrence to public health against melamine-type incidents was recognized by FDA Commissioner Margaret Hamburg in her first public speech upon taking office: “[e]ffective enforcement has many clear benefits to public health. It enables FDA to intercept unsafe or fraudulent products promptly . . . and prevent additional harm. By holding violators accountable, enforcement deters others who would put the public at risk or prey upon vulnerable consumers.”\textsuperscript{261}

A failure to enforce also eviscerates the nutrition value for consumers of premium, nutritious products. In the case of adulterated 100% pomegranate juice for example, consumers are denied the very phytochemicals that account for the unique benefits of pure pomegranate juice.\textsuperscript{262} Permitting the fraud to abound spoils incentives for manufacturers to develop pure, nutritious, and healthy food and beverage products. It also conveys a message to purveyors of healthy products like 100% pomegranate juice — who have spent tens of millions of dollars to research the medicinal and health benefits of their products and to develop, market, and brand the product category for the benefit of the public — that these types of investments may be disgorged by fraud.

Finally, the failure to enforce against economic adulteration is an abdication by the FDA of its public-health responsibilities. Because there is no private cause of action under the FD&C Act, the proponents for prosecuting cheaters were left with one alternative – to file the Purely

\textsuperscript{260} Id.

\textsuperscript{261} Margaret Hamburg, M.D., Effective Enforcement and Benefits to Public Health (Aug. 6, 2009), http://www.fda.gov/NewsEvents/Speeches/ucm175983.htm.

\textsuperscript{262} See Krueger, supra note 15, at B.
Juice lawsuit in the Central District of California for false and misleading labeling and advertising under the Lanham Act.\textsuperscript{263} While the lawsuit was successful, and while “regulation by litigation” may be welcome in some economic sectors, it “has several features at odds with sound health policy – including its cost, its hindsight bias and its adversarial character. . . .”\textsuperscript{264} Depending on litigants to settle matters of economic adulteration also detracts from the core mission of the FDA. Above all else, the FDA is a public health agency.\textsuperscript{265} Its “overriding purpose,” in the words of the U.S. Supreme Court in United States v. Bacto-Unidisk, is to protect public health.\textsuperscript{266} To protect public health, especially in cases of clear fraud, is to be prophylactic and anticipate harm and then enforce the law, not to leave it to the courts to “assign responsibility for harm that has already occurred.”\textsuperscript{267}

\section{2. Good Governance Costs}

Economic adulteration threatens the foundations of good governance in the global food sector. To permit this practice is at best government irresponsibility and at worse is a sign of anarchy. Permitting widespread swindling erodes the fundamental trust between citizens and the government in a society. The connection between maintaining public confidence and good government was recognized FDA Commissioner Margaret Hamburg in her inaugural speech, when she said that “[u]ltimately, an effective enforcement strategy creates public confidence in

\textsuperscript{263} See 15 U.S.C. 1125(a).


\textsuperscript{265} Margaret A. Hamburg and Joshua M. Sharstein, The FDA as a Public Health Agency 2493 The New England Journal of Medicine (June 11, 2009) (the authors are the new commissioner and principal deputy commissioner of the FDA, respectively).


\textsuperscript{267} Sage, supra note 264, at 393.
FDA oversight, which in turn keeps trust in the safety of FDA-regulated products from eroding. 268 In a system replete with economic adulteration, consumers overspend for adulterated product that they perceive to be an authentic high-end product, such as 100% pomegranate juice, which undermines this trust.

The erosion of trust by consumers due to economic adulteration of imported product contributes to a growing cynicism in the food regulatory system. Critics of modern food point to the deliverables of obesity and poor nutrition from the modern food manufacturer. 269 Highly processed foods, juices loaded with sugar and additives stock grocery shelves and provide fodder for spirited criticism towards food and beverage producers, processors, and government bodies. 270 The U.S. government has responded by accelerating its emphasis on good nutrition policy. Three examples illustrate these efforts. First, the government has made a concerted effort to improve the delivery of nutrition information. Congress passed the Nutrition Labeling and Education Act (NLEA) in 1990, which mandated changes in label declarations for collective terms in response to demand by consumers for more information about the nutritional content of food products and the presence of food additives and allergens. 271 Second, in a more recent example, the government has launched new efforts to combat the epidemic problem of obesity, especially amongst obese children who are at risk to have high blood pressure, high cholesterol

268 Id.

269 See e.g., GREG CRITSER, FAT LAND: HOW AMERICANS BECAME THE FATTEST PEOPLE IN THE WORLD (Mariner Books 2004); ERIC SCHLOSSER, FAST FOOD NATION: THE DARK SIDE OF THE ALL-AMERICAN MEAL (Perennial 2002).


271 FORTIN, supra note 53, at 101.
and Type 2 diabetes. Michelle Obama has recently committed her efforts as first lady to the cause of reshaping the diets of children with the goal of reducing childhood obesity. Third, the government has implemented policies to improve nutrition. Even the USDA, whose agricultural policy has primarily been concerned with the performance of the agricultural sector, has played an increasing major role in the implementation of policies to improve nutrition.

The USDA Center for Nutrition Policy and Promotion develops and promotes dietary guidance that links scientific research to the nutrition needs of consumers. These positive efforts are incongruous with the indifference shown by the FDA towards economic adulteration that raises potential significant safety risks and enervates the nutritional value of healthy premium products. Inconsistent approaches to health and nutrition do not help restore consumer confidence or trust in the government’s ability to regulate a troubled food system.

Ineffective enforcement against economically-motivated adulteration also weakens the FDA’s global leadership role in food regulation. Former FDA Commissioner Andrew C. von Eschenbach noted that “[f]or the past century, FDA has been recognized and praised as the gold standard of regulation of food, feed, and medical products throughout the world.” Setting the

\[\text{\textsuperscript{272}} \text{U.S. Centers for Disease Control and Prevention, Childhood Overweight and Obesity, http://www.cdc.gov/obesity/childhood/index.html.}\]


\[\text{\textsuperscript{274}} \text{See S.R. Johnson, How Nutrition Policy Affects Food and Agricultural Policy, American Institute of Nutrition (1994).}\]


gold standard for enforcement against economic adulteration of premium fruit juices, such as 100% pomegranate juice, is not the FDA however, but the New Zealand Commerce Commission. In September 2009, the Commission recalled from supermarket shelves fruit juices imported from Armenia and determined that the juices sold as premium drinks, labeled as 100% pomegranate juice, 100% blackcurrant juice, and 100% peach juice, were in fact not authentic. 277 The warning letter issued by the Commission to Amerenian Imports Limited references the importance of trust to the extent that consumers need to be able to rely on information in order to make an informed choice. 278

3. Economic Costs

Parallel to trust between consumers and government – the linchpin of good governance – is the trust between consumers and industry – the linchpin of economic vitality for honest brokers. The undermining of this trust especially threatens the financial viability of companies producing high-value food and beverage products. Products with pure, natural, and wholesome images are particularly vulnerable to erosion from negative publicity which undermines consumer confidence in the underlying product attributes. Competition is also quashed. 279 Using economic adulteration to reduce input costs may result in cost differences that are significant enough for cheaters to sell adulterated product below product cost for pure products and drive competitors out of business. 280 Non-enforcement encourages less responsible manufacturers to flaunt the law and can force even the most responsible members of the industry

277 FOODNEWS, Watchdog says ‘pure’ juices actually devoid of any juice (July 31, 2009).
279 See Gary F. Fairchild, supra note 60 at 40.
280 See id.
to cut corners in order to meet competition. Faced with this situation, a company must either follow suit and adopt similar rule-breaking behavior, or somehow get the violator to cease its illegal actions. When these companies approach the FDA, they are told that insufficient resources prevent them from taking action. The rest of an industry — left with only expensive, risky, and relatively less powerful remedies — often sinks to the level of the violator, increasing fraud and deception to consumers. In many cases, companies determine that the risk of enforcement is greatly out weighed by the benefits of adulteration and they err on the side of profitability rather than compliance. In order to be competitive, food firms should not need to choose “between doing the right thing and staying competitive.”

The magnitude of the economic cost to industry due to economic adulteration is striking. The GMA report estimates that economic adulteration and counterfeiting of global food and consumer products costs the industry $10 to $15 billion per year. The report notes that the cost of one adulteration incident averages between two to fifteen percent of yearly revenues for a company. For a ten billion dollar company, this revenue loss translates into roughly $400 million dollars; for a small $500 million dollar company the impact is approximately $60 million dollars. Where economic adulteration leads to a food safety problem, the costs are even greater. In the case of melamine, more than thirty local and global milk brands were affected and the adulteration resulted in $5 billion dollars of lost sales and the bankruptcy of

\footnotesize{\begin{itemize}
  \item 281 Id.
  \item 282 ATKearney, supra note 170 at 3.
  \item 283 Id.
  \item 284 Id.
\end{itemize}}
The cost of a food safety disaster in the U.S. was demonstrated in 2009, when intentional sales of salmonella-contaminated products caused the peanut butter market to shrink 25% and forced the Peanut Corporation of America to file for bankruptcy.\textsuperscript{286}

4. Social Costs

In addition to fracturing the links of trust between government and industry to consumers, unchecked economic adulteration also spoils the opportunity for linkage between farms and consumers. Even farms, long a symbol of the Jeffersonian ideal in America, along with the subsidy programs that incentivize production, have been censured for producing large quantities of food product, such as corn for high-fructose corn syrup, that contribute to obesity and poor nutrition.\textsuperscript{287} A nutritionally-bankrupt food supply tears at the social connections between farmers and consumers. In this much malaised sector, non-subsidized pomegranate farms and the juice they provide are a breath of fresh air. 100% pomegranate juice allows pomegranate farmers who produce the appealing product to forge a trust linkage with consumers who are searching for healthy, nutritious choices. Adulteration thwarts this linkage to the detriment of consumers, farmers, and the agriculture sector.

V. Conclusion

In his opening remarks at the FDA’s adulteration meeting, Dr. Randall Lutter, FDA’s Associate Commissioner for Policy and Planning, noted the scope of the problem of economic adulteration by stating:

\textsuperscript{285} Id.

\textsuperscript{286} Id.

I need to stress something else, and this is very important for everyone here. This is not solely an FDA responsibility addressing this problem. It should never be construed as such. Every manufacturer and seller of an FDA-regulated product or products or more broadly, than can be adulterated and can harm people as a result of adulteration, has a responsibility to the American public and to ensure that harmful adulteration does not occur. We are bringing you here in part to get you all to recognize that this is not solely an FDA responsibility; this is one that industry shares with us. We need you to recognize that we need your help.  

While the spirit and intent of Dr. Lutter’s remarks are appropriately tuned to calibrate the expectations of what the FDA can do given its limited resources, promoting “shared responsibility” with manufacturers also implies that the FDA intends to take action. Taking enforcement action against economic adulterators, including that of imported 100% pomegranate juice concentrate, would reflect a measured and deliberative approach that appreciates the real costs of economic adulteration. It would send a message vital in today’s global food system that cheaters do not prosper, and stem what presages to be an increase of cheating proportionate to the continued expansion of international food trade. It would safeguard the health interests of consumers and the integrity of the food market. It would build bonds of trust between consumers and the government, between consumers and industry, and between consumers and pomegranate farmers that would help ensure a more safe and nutritious food supply, restore integrity in the food supply, and shore up confidence in the ability of the government to regulate the food supply.

The pomegranate is a durable fruit and its derivative, healthy 100% pomegranate juice product stands as a symbol of the good that can be harvested from a global food system – a product that is healthy and appealing in sundry ways. It is also unfortunately a symbol of the

288 FDA Public Meeting, supra note 14, at 3.
harm of globalization – a victim of food swindling that portends serious health, social, and safety consequences. The durability of modern food regulatory bodies in this global food society, including the FDA, will depend on their ability to stop the cheating and preserve the good health and well being of consumers.
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