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Signature:

Maria Vyshnya Aslam

Date

Economics of Precautionary Messages: Labeling Health Risks

By

Maria Vyshnya Aslam
Doctor of Philosophy

Economics

David E. Frisvold, Ph.D.
Advisor

Maria Arbatskaya , Ph.D.
Committee Member

David H. Howard, Ph.D.
Committee Member

David Jacho-Chavez, Ph.D.
Committee Member

Accepted:

Lisa A. Tedesco, Ph.D.
Dean of the James T. Laney School of Graduate Studies

Date

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By

Maria Vyshnya Aslam
M.A., Emory University, 2013
M.A., Economics Education and Research Consortium, 1999

Advisor: David E. Frisvold, Ph.D., Vanderbilt University

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Abstract

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This dissertation provides a comprehensive analysis of the risk information campaigns familiarizing consumers with the hazardous product attributes. Recently the public is overwhelmed with warnings about health, safety, and environmental hazards, some of which have disappointing effects on consumer safety. This calls for identifying the limitations in conveying safety messages to the vulnerable population.

As a policy example, this dissertation focuses on initiatives informing the public of the most dangerous allergens, responsible for 90 percent of allergic reactions. The first chapter examines different ways of communicating health risks and compares voluntary and mandatory posting of the allergy warnings. Using difference-in-differences and difference-in-differences with endogenous stratification, I demonstrate that the voluntary display of harmful ingredients is associated with a sizable increase in the demand for medical services, while mandatory disclosure results in a steady decline in the number of vulnerable patients seeking medical help.

Another empirical paper (chapter 3) focuses on consumer reaction to health risk messages. I contrast consumers with the higher and lower allergen susceptibility using a difference-in-differences setup and a two-step procedure. Surprisingly, the policy improves health outcomes of patients with lower allergen susceptibility. However, when controlling for the exogenous variation in patients' prior expectations about product safety, I find no difference in reaction to warnings regardless of consumer risk sensitivity. Comparison of the "mass" regulatory initiatives and personalized warnings shows no link between the mass campaigns and health improvements unless consumers have access to individualized warnings.

My theoretical paper (chapter 2) examines the interactive effects of regulation and litigation in effecting the equilibrium consumer and firm care in avoiding unsafe ingredients. The main novelty is in recognizing that consumer warning-reading effort is endogenous, and it is determined by various factors, including liability system and firm care. I found that from consumer perspective, equilibrium firm and consumer care are strategic substitutes, while for a firm they are complements. This calls for improving the warning visibility and consumer risk perception, which increase both the equilibrium consumer and firm care. Stronger liability, however, shifts the burden of care from consumers to firms with an overall ambiguous effect on expected harm.

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CHAPTER 1

VOLUNTARY VS MANDATORY DISCLOSURE OF RISK INFORMATION: EVIDENCE FROM FOOD ALLERGEN LABELING REGULATION

Abstract

This paper focuses on the risk information campaigns familiarizing consumers with the hazardous attributes of products and compares voluntary and mandatory displays of warning messages. To determine the efficacy of the risk information campaign, I examine food allergen labeling regulation that informs consumers if the food contains any of the allergens responsible for the majority of allergic reactions. Using difference-in-differences and difference-in-differences with endogenous stratification, I demonstrate that the voluntary display of harmful ingredients is associated with a sizable increase in demand for medical services, while mandatory risk disclosure results in a steady decline in the number of vulnerable patients seeking medical help. This result demonstrates that the disclosure of product risk characteristics might adversely affect consumers' health if the disclosure policy is not chosen carefully.

Introduction

Voluntary disclosure of product characteristics has become increasingly popular as a mechanism to provide quality information. Industries, concerned about the lemon problem, establish agencies to collect and distribute product information. Manufacturers notify consumers about the quality of their products through branding, warranties, or by using third party certifiers responsible for accreditation or licensing (Dranove and Jin, 2010). Nevertheless, in most cases, firms inform customers about the positive or neutral attributes of their products. For instance, longer warranties signal higher product quality.

However, what if a firm needs to inform consumers about explicit harm to their health associated with a given product? For example, an explicit warning on a cigarette pack has to notify buyers that smoking may cause fatal lung disease, stroke, or heart disease. Or a food label needs to warn consumers about ingredients that may cause severe allergic reactions or cancer. Will market mechanisms ensure sufficient safety incentives that stimulate manufacturers to disclose the risks willingly?

The goal of this paper is to understand if the disclosure of health risks equips customers with sufficient information to avoid risky products, to examine different ways of communicating risk information, and to compare their impact on the utilization of medical services by the vulnerable consumers. I compare voluntary disclosure, which induces manufacturers to post health risks, to disclosure mandates that are compulsory for all firms. Comparing the impact of voluntary and mandatory disclosure of risk information is a topic relatively undeveloped in economic literature. A dominating theory of "unraveling results" suggests that if the quality of information is unverifiable, goods are of experience type, communication between buyers and sellers is costless, and consumers hold rational expectations, then sellers will always willingly disclose the information

about product quality. Otherwise, rational consumers will infer nondisclosure as having the lowest quality (Viscusi, 2007; Jovanovic, 1982; Grossman, 1981; Milgrom, 1981). This implies that government-mandated disclosure is inefficient and unnecessary (Dranove and Jin, 2010; Viscusi, 2007; Schwartz, 2005). However, there are several reasons why voluntary disclosure may not be as efficient as mandatory disclosure. First, voluntary disclosure allows for less coordinated display standards. If different wording affects consumers' ability to locate the message, voluntary labeling may not significantly affect their behavior. If consumers experience difficulty in assigning the proper amount of risk to a product, they may buy a more risky product assuming it to be safer than it actually is (Hellier et al., 2006; Magat et al., 1992). Second, if the disclosure of health risks is voluntary and recipients of the information signal are not fully informed of the risks they face, then producers may choose not to post information about lower quality goods, such as ingredients causing more severe reactions in consumers (Roses, 2011; Kamenica and Gentzkow, 2011; Porter, 2003; Formanek, 2001; Mathios, 2000; Fishman and Hagerty, 1990). The consequences of this selective disclosure of unsafe ingredients might be detrimental to consumers who erroneously consider products without health warnings to be safe. In contrast, mandatory disclosure does not allow for manufacturer selective bias, and it typically sets uniform criteria for positioning and wording a risk message. This makes a warning more visible and clear (Board, 2009; Magat and Viscusi, 1992). However, if an industry establishes high standards for its member firms, voluntary labeling may adequately equip the public with information about product quality. In this case, the impact of the mandate might be comparable to standards established by the market mechanisms (Dranove and Jin, 2010; Dranove, 1988).

As an example of a risk information campaign, this paper focuses on the industry and government regulatory initiatives designed to familiarize consumers with allergen additives in foods. The National Food Processors Association (NFPA) industry guidelines (April 2001) advocated vol-

untary disclosure of hazard information. The federal "Food Allergen Labeling and Consumer Protection Act" (FALCPA) mandated food allergen labeling (July 2006). Both regulatory initiatives aim to inform allergic consumers if particular foods contain any of the most dangerous allergens, responsible for 90 percent of all allergies, and require manufacturers to label the allergens "in plain and clear language." Furthermore, the federal mandate sets a uniform standard for positioning the hazardous information on labels and bans fine prints, thus making the warnings more noticeable for consumers.

Food allergen labeling is a unique example for assessing the influence of alternative risk information campaigns, which allows this study to make four main contributions to the literature. First, the existing literature mostly concentrates on *mandatory* information disclosure (Dafny and Dranove, 2008; Hastings and Weinstein, 2008; Figlio and Lucas, 2004). There are only a few empirical papers looking at both policies. Mathios (2000) uses voluntary disclosure as a control period for evaluating the mandatory display of nutrition labels. Jin and Leslie (2003) compare voluntary postings of restaurant hygiene cards to a mandate, implemented only a couple of months later. The timing of the regulation explains a small in magnitude difference between the impacts of both policies, since restaurants may have already anticipated a change to mandatory disclosure in the near future. In contrast to previous studies, mandatory display of allergens on food labels went into effect only five years after the voluntary guidelines. This allows contrasting the impact of both policies in the short and medium run. Second, the existing literature mainly concentrates on disclosing the *favorable* attributes of a product. However, recent experimental and neuroeconomics literatures document that positive and negative signals are recorded differently by the brain (Eil et al., 2011; Ertac, 2011; Caplin et al., 2010, 2008). Therefore, requirements for the positioning and wording of positive information may not be appropriate for revealing risks. This study addresses the recent neuroeconomics findings and provides the early evidence of the impact of *negative* quality

information on consumers' behavior. Third, vulnerable consumers experience an allergic reaction within couple of hours after their contact with an allergen (NIH NIAID, 2011) or (Bischoff, 2007; Venter et al., 2006). Therefore, food allergen labeling permits an analysis of the *immediate* effect of the health warnings after they are implemented. Finally, according to epidemiological studies, there is a limited cure for food allergies, and the most successful method to manage allergic reactions is to avoid food containing allergens (Boyce et al., 2010; Vierk et al., 2007). Thus, the availability of information about product quality becomes crucial.

This paper analyzes the impact of voluntary and mandatory food allergen labeling on the morbidity of allergic consumers utilizing hospital outpatient department (OPD) records from the National Hospital Ambulatory Medical Care Survey (NHAMCS) for the period of 1997 – 2010. Since both information campaigns were nationwide, I use a difference-in-differences (DID) setup to compare the number of OPD visits with food allergies to two synthetic control groups: the number of OPD patients with non-allergy diagnoses and patients with non-food allergies. The former accounts for unobserved advancements in medical technology targeting patients with particular symptoms, while the latter controls for the unobserved advancements in treating allergies. Since the same OPD may admit patients with food allergies and patients with control diseases, I use a multivariate two-step framework, where the first step addresses control diseases, and the second step focuses on food allergies controlling for the number of reference group diseases estimated from the first step (Cameron and Trivedi, 2013; Imai, 2011). Conventional DID estimates the impact of allergen labeling on the number of food allergies documented in OPDs, while DID with exogenous stratification evaluates the effect on the latent demand for medical services among all consumers who might experience allergic reactions.

I demonstrate that the voluntary display of harmful ingredients results in a three to five times increase in the use of OPD medical services among consumers diagnosed with food allergies, while

the mandatory health warnings reduce the use of medical services by 25 – 50 percent, depending on a patient age. This effect is robust for different patient types, different comparison groups, and different specifications. Theoretical and epidemiological literature allows for several explanations of this difference in the impact of both policies. First, less coordinated display standards, allowed under the voluntary scenario, may affect consumers' ability to locate and understand the message. Second, if manufacturers are allowed to disclose the risks voluntarily and consumers are not fully informed of the risks they face, firms may choose not to disclose information about lower quality products (e.g., products with a higher content of harmful ingredients or products containing the most dangerous ingredients), and consumers may erroneously consider products without warnings to be safer. This study does not allow clear differentiation between these two reasons. However, in the case of food allergen labeling, voluntary and mandatory standards for displaying allergen content are very similar. The only difference introduced in the federal mandate - banned fine prints and clearer requirements about positioning the warning on a label - might explain some difference in the effect. However, these changes are unlikely to result in a four-time increase in the demand for medical services in the post-voluntary period. Therefore, a manufacturer's selective nondisclosure of more harmful ingredients seems to be a plausible explanation. Regardless of the reasons, mandatory disclosure of health risks seems to provide consumers with the information sufficient to avoid unsafe products, while voluntary disclosure results in a sizable increase in morbidity among the vulnerable consumers.

Disclosure of Allergen Content in Foods

The first attempt to notify consumers about potential allergens occurred in 1938 when Congress passed the Federal Food, Drug, and Cosmetic Act (*FD&C Act*). The *FD&C Act* and its amendments focused predominantly on poisonous ingredients in food, pesticides, and unsafe

food additives. The latter includes food colors, flavors, preservatives, nutrients, and processing aids (US Food and Drug Administration, 1938). According to the *FD&C* Act, the list of food additives safe for human health is determined by the FDA. The only additives that are not subject to FDA testing and approval are "prior sanctioned" and "GRAS", or "Generally Recognized as Safe", substances. The former were approved by the FDA before the 1958 Food Additives Amendment, and the later have been extensively used in the past with no known harmful effect and are believed to be safe.

The *FD&C* Act defines unsafe food ingredients; however, it does not ban their use. It also allows for some ambiguities in labeling those substances. First, labeling allows for the generic listing of colors and flavors (e.g. "natural flavoring") without specifying particular hidden allergens contained in those flavors or colors, such as milk or soy protein (Fortin, 2006; Joshi et al., 2002). Second, "incidental" or "processing" additives are exempt from ingredient labeling. For example, if lecithin is used to separate food from the processing equipment, it would not be mentioned on the label. Finally, the *FD&C* Act does not prevent manufacturers from using multiple names for the same type of ingredient. For instance, wheat may be labeled as "semolina", and egg protein - as "albumin" (Munoz-Furlong, 2001). As a result, complex ingredient terminology and label ambiguities have compromised the ability of consumers to determine product safety. According to Preeti et al. (2002), only 20 percent of parents of children with food allergies were able to correctly identify common food allergens.

In 2000, the FDA started a nationwide campaign aimed to address ambiguities in the existing food allergen labeling legislation. It has presented information on allergen risks and labeling requirements at more than a dozen locations nationwide, and it propagated unified labeling requirements at several workshops with the food industry, trade associations and consumer advocate groups (Formanek, 2001). In response, in April 2001 the National Food Processors Association (NFPA)

released an industry "Code of Practice" for managing food allergens. The code called for the voluntary listing of the eight most common food allergens, which account for about 90 percent of all food allergies. This list includes milk, eggs, fish, Crustacean shellfish, tree nuts, peanut, wheat, and soybeans. The code advocated listing the common name for the allergic substances contained in food in "plain and clear language" (Formanek, 2001).

FALCPA further advanced in familiarizing consumers with allergic substances. This law, introduced by the FDA and enacted in July 2004, went into effect in January 2006. Similar to NFPA guidelines, it requires listing the major allergens "in plain and clear English". Furthermore, it sets a uniform standard for positioning the hazardous information on labels. According to FALCPA (FDA, 2009), there are two possibilities to label the allergens. First, the label with the statement "contains (allergen source)" may immediately follow or be adjacent to the list of ingredients (e.g. "contains peanuts"). Second, the allergens may be mentioned in the parentheses immediately after the ingredient ("casein (milk)"). Furthermore, the mandate bans fine prints, which makes the warning message more visible.

There are several nuances about what food types or ingredients are subject to the federal labeling legislation (Fortin, 2006; Wilson, 2004) and (USDA, 2006). First, the new labeling requirements do not apply to raw meat, poultry, and eggs, all of which are regulated by the USDA's Food Safety and Inspection Service. Second, FALPCA does not apply to foods placed in a wrapper, a carry-out box, or other container *after* being ordered by a consumer. Third, manufacturers may also petition the FDA for an exemption if they provide scientific evidence that their food ingredients do not contain allergic protein and are "safe for human health". Finally, the FDA does not require manufacturers to re-label or recall their products if they were labeled before January 2006 - the law's effective date.

Data

I evaluate the impact of the risk information campaigns by looking at consumers' morbidity using hospital outpatient department records from the restricted version of the National Hospital Ambulatory Medical Care Survey (NHAMCS) for the period of 1997 – 2010. NHAMCS is a pooled cross-section individual-level dataset documenting daily visits to hospital outpatient departments (OPDs). Publicly available NHAMCS reports on three major physician's diagnoses of a current visit, the urgency of a visit, patient insurance and socio-economic characteristics, and a set of OPD characteristics (Appendix 1.A). The restricted version of NHAMCS additionally contains OPD geographic identifiers and a set of Census variables reflecting consumers' ability to read and understand the warnings - patient education, income, and English literacy. Since the restricted socio-economic variables based on patient's zip code are not reported for 1997 – 2000, I extend NHAMCS with the corresponding variables from the Census. Census variables are based on OPD county codes¹ and are available for the entire period of 1997 – 2010.²

NHAMCS, the core source of our data, offers several advantages for our purposes. First, it is one of the few national samples containing records for as early as 1990s, which allows to pioneer at evaluating the effect of a voluntary risk disclosure and contrasting it to an impact of the mandate. Second, this dataset identifies a distinct allergy type of a visit (Appendix 1.B).

An important limitation of this dataset is that it reflects only patients visiting OPDs³. At the

¹In the Census these variables are available at OPD zip and county level. Comparing zip and county levels, I prefer the latter, since counties are larger, and they include more potential patients. This reasoning does not apply to well-known health centers such as John Hopkins or Emory Clinic, which admit patients from all over the US. But these centers are mainly outliers, while other hospitals are more focused on providing services to the local public.

²Since using OPD rather than patients' county codes may result in less precise estimates of the socio-economic characteristics, I utilize both the Census and restricted NHAMCS data. Census data (based on OPD county codes) is available for the entire period of 1997 – 2010, while NHAMCS data (based on patients' zip codes) is available for 2001 – 2010 only (Appendix 1.C: Tables 1.10-1.11). Then I focus on 2001 – 2010 (years that contains information from both Census and NHAMCS files), compare the coefficients based on OPD county codes to those based on patients' ZIP codes and assess the bias. Using the bias, I conclude that our estimates, based on OPD county codes, provide only the lower bound of the effect.

³An alternative nationally representative source of non-urgent medical care is NAMCS, which provides records for

same time, several groups of consumers with food allergies might not be recorded in OPDs. First, consumers having mild allergies might mitigate symptoms of their disease by using less intensive remedies, such as vitamins, skin creams, eye drops, nasal sprays, etc (Sicherer, 2011; Bischoff, 2007; Kalliomäki et al., 2007). For instance, patients with mild food dermatitis are less likely to have their allergic reactions if they apply skin moisturizers that improve skin barrier function in atopics (Proksch et al., 2008; Loden, 2005). Even though the share of milder allergies is unknown, these patients can hardly be considered a core policy target group, as they may cope with their disease with very limited medical support.

Second, patients with more intensive allergic reactions might need allergy medications and they might attend an OPD to get their prescription. However, they are likely to choose prescription rather than over-the-counter (OTC) drugs if those are covered by their insurance (Petersen, 2002). It might be expected that some uninsured patients with above-average allergy severity may visit an OPD if they need allergy diagnostics, or if the OTC medications do not help them to combat their symptoms. However, according to our data (Table 1.2), the share of uninsured OPD patients is fairly low. The share of self-pay OPD patients with food allergies does not exceed 9 percent, and the share of no charge patients is barely reaching 2 percent. Importantly, the need for prescription drugs for insured and uninsured patients does not depend on availability of allergy medications over-the-counter: the list of allergy-related medications consists of a wide range of easily substitutable options, many of which were available over-the-counter for the entire period of 1997 – 2010 (Boyce et al., 2010; Bischoff, 2007). Therefore, medical insurance should not be a leading factor causing the change in OPD food allergy visits.

non-federal employed office-based physicians. It contains only a few observations for any allergy type, including food allergies. This might be because allergies are predominantly diagnosed using physical exam tests and patient medical history. Physical exam tests are generally administered in hospitals or medical offices, which is a serious limitation for non-institutionalized medical practitioners surveyed by NAMCS (Niggemann and Beyer, 2007; Roberts, 2005). A retrospective medical history presumes a doctor has seen the patient before (Gendo and Larson, 2004). As a result, limited records of food allergies in NAMCS might signify that the majority of food allergy diagnoses are confirmed by physical exam tests or patient medical history and recorded in OPDs, surveyed by NHAMCS.

Lastly, the opposite spectrum of food allergy distribution - life-threatening cases - is less likely to be recorded in OPDs, as these patients might need ER medical services or hospitalization. The composition of OPD food allergy visits (Table 1.1) supports this hypothesis: the majority of OPD allergies are represented by milder cases such as skin reactions or allergies to milk, while the share of life-threatening cases, such as an allergy to peanuts, seafood, or incidents of anaphylactic shock, does not exceed 3.3, 3.2, and 0.1 percent respectively. Even though OPD records omit life-threatening allergies, the share of these cases does not exceed 5 percent of all food allergies (Vierk et al., 2007).

Based on the characteristics of NHAMCS OPD records, this study ignores the upper and lower tails of food allergy distribution and focuses on the largest segment of food allergies - visits with the average and above-average severity.

Methodology

Food Allergies and Their Synthetic Controls

I evaluate the efficacy of the information campaigns by looking at the number of food allergy visits and analyze if it declines after the voluntary or mandatory disclosure of the allergen content in foods.⁴ Since both information campaigns were national, I use a difference-in-differences (DID) setup and compare the full set of food allergies to a convex combination of non-allergy diseases (Abadie et al., 2010, 2003). This allows controlling for unobserved advancements in medical technology targeting particular disease symptoms. A synthetic control group is represented by

⁴As a robustness check, I evaluate if the information campaign affects the intensity of allergies. I zoom in on patients, who visited hospital outpatient departments and who were diagnosed with food allergies, and analyze if the health warnings reduce the share of acute cases compared to non-urgent cases. As for acute cases, I differentiate between less informed consumers who have been living with their disease for less than three months and compare them to more informed consumers. Since the latter category has been living with allergies for longer, they have more information about how to combat their disease, and thus they are likely to benefit the most from the information disclosure. According to our results (Appendix 1.C, Table 1.12), risk information campaigns primarily affect the number of OPD patients diagnosed with food allergies rather than the intensity of their allergic reactions.

a weighted average of non-allergy diagnoses, with weights chosen so that the resulting synthetic "food allergies" best reproduce the values of a set of predictors of OPD food allergy visits prior to 2001, when the first allergen labeling regulation went into effect. My outcome variable of interest is the number of visits with food allergies or control group diseases per 10,000 patients, recorded at an OPD h located at a states s at time period t. The set of predictors of the outcome variable in the pre-intervention period includes patient socio-economic characteristics including their race, gender, and age; patient insurance characteristics; and hospital characteristics including their location and ownership status (Table 1.2) ⁵.

Table 1.1: **Composition of Food Allergies**, frequencies

	Food Allergies			Food Allergies: age over 15			Food Allergies: age 15 and younger		
	A (1)	B (2)	C (3)	A (4)	B (5)	C (6)	A (7)	B (8)	C (9)
Food Allergies: Diagnoses Composition									
Skin reactions due to food	0.382	0.324	0.299	0.295	0.281	0.158	0.530	0.357	0.359
Allergic gastroenteritis due to food	0.000	0.061	0.102	0.000	0.000	0.002	0.000	0.107	0.144
Allergic rhinitis due to food	0.000	0.005	0.003	0.000	0.000	0.000	0.000	0.008	0.004
Anaphylactic shock due to food reaction	0.001	0.004	0.001	0.000	0.000	0.003	0.002	0.007	0.000
Other adverse food allergic reactions not elsewhere specified	0.000	0.034	0.141	0.000	0.012	0.016	0.000	0.049	0.195
Allergy to milk products	0.590	0.484	0.417	0.669	0.567	0.790	0.456	0.421	0.259
Allergy to eggs	0.000	0.013	0.024	0.000	0.000	0.000	0.000	0.023	0.034
Allergy to seafood	0.032	0.102	0.023	0.044	0.239	0.030	0.013	0.072	0.021
Allergy to peanuts	0.000	0.000	0.033	0.000	0.000	0.000	0.000	0.000	0.047
Number of cases	173101	473659	63973	87969	192334	119012	85132	292807	528118
Number of cases per 10,000 OPD patients	4.28	11.25	10.5	3.39	6.4	4.64	4.76	20.85	31.06

Columns: A - pre-regulation period (1997-2000); B - voluntary risk information disclosure (2001-2005); C - mandatory risk information disclosure (2006-2010).

Source: NHAMCS outpatient department records for 1997-2010.

The set of non-allergy diagnoses (the "donor pool") consists of diseases that satisfy the following criteria. First, they have both chronic and acute phases, which match the composition

⁵Tables 1-2 report the weighted number of OPD visits. The actual number of visits with food allergies and non-allergy control diseases varies around 600-800 observations per time period, and the actual number of non-food allergies vary between three and five thousand cases. The weighting does not affect the outcome variable, defined as the number of OPD visits with food allergies or control group diseases ("numerator visits") per 10,000 OPD patients ("denominator visits"). This demonstrates no systematic difference in behavior of the "numerator" and "denominator" patients. If this difference existed, sample weights would have corrected an endogenously varying probability to sample a particular OPD visit. The reasons leading to sampling endogeneity are discussed in Section IV.B.

Table 1.2: Food Allergies and their Synthetic Controls by Selected Characteristics

	Food Allergies			Control Group Diseases (i): Non-Allergy Cases			Control Group Diseases (ii): Non-Food Allergies		
	A (1)	B (2)	C (3)	A (4)	B (5)	C (6)	A (7)	B (8)	C (9)
Urgency of Visit Composition , frequencies									
Acute Reactions, including	0.35	0.37	0.36	0.79	0.82	0.76	0.49	0.48	0.45
<i>Less informed patients</i> (onset within three months of this visit)	0.24	0.29	0.34	0.73	0.75	0.70	0.34	0.35	0.32
<i>More informed patients</i> (three months and over)	0.11	0.07	0.03	0.07	0.07	0.07	0.15	0.13	0.14
Non-Acute Cases, More informed patients	0.65	0.64	0.64	0.19	0.18	0.24	0.49	0.52	0.55
Patients' Socio-Economic Characteristics , frequencies									
Mean Patient's age, years	33.88 (7.67)	23.3 (3.46)	17.61 (4.33)	33.15 (0.74)	31.55 (0.89)	34.59 (1.25)	28.84 (0.94)	28.63 (1.14)	26.33 (1.48)
Patient Race: White	0.74	0.67	0.49	0.79	0.78	0.64	0.63	0.62	0.56
Patient Race: Black	0.17	0.30	0.30	0.18	0.19	0.17	0.33	0.33	0.29
Patient Race: Asian	0.07	0.03	0.02	0.02	0.02	0.01	0.03	0.02	0.01
Patient Sex: Female	0.61	0.55	0.54	0.55	0.57	0.58	0.59	0.60	0.58
Established Patient	0.94	0.77	0.86	0.79	0.85	0.83	0.88	0.88	0.88
Patients' Insurance Characteristics , frequencies									
Private	0.44	0.57	0.47	0.42	0.44	0.44	0.36	0.35	0.40
Medicare	0.17	0.05	0.07	0.13	0.13	0.17	0.08	0.09	0.09
Medicaid	0.21	0.34	0.41	0.24	0.30	0.34	0.34	0.42	0.45
Worker's Compensation	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Self-Pay	0.07	0.02	0.09	0.12	0.08	0.09	0.08	0.05	0.05
No Charge	0.00	0.02	0.01	0.01	0.01	0.02	0.04	0.03	0.02
Other	0.08	0.02	0.06	0.05	0.03	0.04	0.05	0.03	0.03
OPD Characteristics , frequencies									
MSA area	0.74	0.94	0.94	0.80	0.72	0.77	0.88	0.84	0.85
Location: Northeast	0.31	0.31	0.33	0.18	0.16	0.17	0.28	0.31	0.27
Location: Midwest	0.13	0.24	0.18	0.33	0.38	0.41	0.30	0.27	0.30
Location: South	0.42	0.28	0.43	0.32	0.32	0.28	0.27	0.29	0.32
Ownership: Voluntary non-profit	0.74	0.85	0.83	0.73	0.80	0.76	0.67	0.75	0.76
Ownership: Govern., non-Federal	0.21	0.13	0.17	0.21	0.18	0.23	0.28	0.24	0.23
Ownership: Proprietary	0.05	0.02	0.00	0.06	0.02	0.01	0.05	0.01	0.01
Census Variables (OPDs county) , means									
BA degree	24.46 (1.99)	27.36 (1.18)	29.38 (0.97)	23.44 (0.82)	25.19 (0.93)	27.26 (0.89)	26.37 (1.05)	27.11 (0.81)	28.55 (0.99)
Do not speak English	14.00 (1.56)	18.28 (1.61)	14.96 (2.25)	14.10 (0.95)	13.75 (0.81)	13.73 (0.77)	19.32 (1.02)	19.08 (1.06)	16.44 (1.01)
Foreign born	8.61 (0.64)	11.97 (1.19)	9.68 (1.41)	8.70 (0.60)	8.91 (0.57)	9.19 (0.55)	12.47 (0.71)	12.73 (0.76)	10.83 (0.69)
Household income, ths USD	23.98 (0.79)	23.25 (0.49)	23.27 (1.09)	24.19 (4.45)	22.77 (4.78)	23.03 (4.74)	24.36 (4.56)	22.79 (3.99)	23.01 (4.82)
Below poverty	12.55 (0.65)	14.38 (0.45)	15.82 (0.82)	12.95 (0.45)	13.56 (0.33)	14.98 (0.35)	14.16 (0.48)	14.69 (0.36)	15.78 (0.37)
Number of cases, thousand patients	173.1	473.6	635.9	16664	18020	16967	8463.7	11700	10365
Number of cases per 10,000 OPD patients	4.28	11.25	10.5	133.4	107.5	97.5	42.5	39.3	31.9

See Table 1.1 notes. Source: NHAMCS outpatient department records and Census data for 1997-2010.

Since both voluntary and mandatory allergen disclosure affects the entire country, I compare food allergies to a synthetic control group represented by a weighted average of control diseases, with weights chosen so that the resulting synthetic "food allergies" best reproduce the values of a set of predictors of food allergy visits prior to 2001, when the first allergen labeling regulation went into effect. The set of predictors includes patient socio-economic and insurance characteristics and OPD characteristics (see Table 1.2). Synthetic Control Group (i) consists of non-allergy diagnoses, and it controls for unobserved advancements in medical technology targeting symptoms similar to food allergies. Synthetic Control Group (ii) consists of non-food allergies, and it controls for medical advancements in treating allergies.

(i) Synthetic Control=0.466*Bronchitis+0.31*Pneumonia+0.224*Skin Reactions;

(ii) Synthetic Control=0.138*Allergic Asthma+0.862*Allergic Conjunctivitis

of food allergies. Second, the diseases manifest symptoms observed in food allergies. This allows controlling for unobserved advancements in medical technology targeting patients with particular symptoms. Third, they are represented by non-allergy diagnoses. Since allergies are provoked by particular genes, patients who do not have these genes do not suffer from allergies (Nowak-Wegrzyn et al., 2001; Venter et al., 2006). Therefore, disclosure of allergen content in foods does not affect patients not having those genes even though symptoms of their disease are similar to allergies. Among all donor pool diseases, I choose those with minimum pseudo distance between the synthetic control unit and food allergies, and those with the trajectory of the outcome variable similar to food allergies in the pre-treatment period (Abadie et al., 2010, 2003).

As a robustness check, I compare food allergies to a different synthetic control represented by non-food allergies. This group aims at controlling for medical advancements that relieve allergy symptoms (e.g. sales of allergy-related medications or their over-the-counter availability). Including those variables directly into the model is rather problematic. First, the list of allergy-related medications consists of a wide range of options including pills, liquids, inhalers, nasal sprays, eye drops, skin creams and injections (Boyce et al., 2010; Bischoff, 2007). Some of them - epinephrine, mast cell stabilizers, immunomodulators, some antihistamines and corticosteroids - target more intensive or life threatening allergic reactions and therefore require a prescription. Dozens of others - decongestant sprays, eye drops, skin creams etc. - address less intensive allergies and are available over-the-counter. Second, the availability of these medications over-the-counter changes over time. For instance, Claritin, having the highest market share among allergy-related medications (37.5 percent of sales), became available OTC in December, 2002. However, by that time the first-generation antihistamines such as Benadryl were already available OTC. Moreover, availability of these medications over-the-counter predominantly favors consumers without health insurance, while insured patients might switch to prescription drugs (e.g. Allegra or Zyrtec) if those drugs are covered

by their insurance (Petersen, 2002). An alternative synthetic control specification allows both the treatment and control group to be equally affected by the medical advancements in anti-allergen medications. In this way, I indirectly control for fluctuations in the OPD allergy visits driven by technological improvements in allergy medications or their availability on the market.

While constructing the alternative control group that consists of non-food allergies, I excluded from the "donor pool" all allergies having symptoms frequently observed in food allergies and use only those with symptoms rare in food allergies. In this way I exclude a wide range of non-food allergies that might be misdiagnosed with food allergies (Niggemann et al., 2007; Roberts, 2005). The remaining "donor pool" consists of non-food allergies that might only be triggered by the food allergies (Nowak-Wegrzyn et al., 2001; Venter et al., 2006). Since the remaining non-food allergies might still be indirectly affected by food allergies, comparing food allergies to the second synthetic control group - allergies with symptoms rare in food allergies- provides the lower bound of the effect of the allergen labeling regulation.

Composition of food allergies is reported in Table 1.1, while characteristics of patients attending OPDs with food allergies and control group diseases are reported in Table 1.2. The non-allergy control group is fitted the best by bronchitis, pneumonia, and skin reactions. This matches the composition of food allergies represented predominantly by skin reactions and allergies to dairy products with a smaller fraction of allergy to seafood, allergic gastroenteritis, and food-induced anaphylactic shock. The second control group (non-food allergies) consists of allergic asthma and conjunctivitis not common among food allergies. Both control groups might be considered the adequate "synthetic food allergies," since they closely match food allergies in the pre-intervention period for the full set of synthetic control predictors including patients' socio-economic and insurance characteristics and hospital characteristics (Table 1.2: columns 4, 7, and 1 respectively).

Estimation

To evaluate the impact of food allergen labeling campaigns on food allergies and control group diseases, I use an OPD h located in a state s at time period t and contrast the number of OPD visits with food allergies per 10,000 OPD patients to those with the reference group diseases per 10,000 OPD patients. However, in this setting the same OPDs may admit patients with food allergies and patients with the reference group diseases. Therefore, I use a multivariate two-step framework, where the first step addresses the number of control group diseases, and the second step focuses on food allergies controlling for the number of the reference group diseases estimated from the first step (Cameron and Trivedi, 2013; Imai, 2011):

$$A_{hst} = E[A_{hst} | C_{hst}, Regulation_{1t}, X_{1hst}, \delta_{1h}, \tau_{1t}, u_{hst}] \quad (1.1)$$

$$C_{hst} = E[C_{hst} | Regulation_{2t}, X_{2hst}, \delta_{2h}, \tau_{2t}, e_{hst}] \quad (1.2)$$

where C_{hst} measures control group diseases, A_{hst} represent food allergies, X_{hst} is a set of OPD characteristics as well as patients' socio-economic and health insurance characteristics, averaged at a hospital level (Appendix 1.A), δ_{1h} stand for state fixed effects, τ_{1h} represents polynomial time trend and months fixed effects. Months fixed effects account for the seasonality of allergies. Polynomial time trend is a flexible tool to capture the information specific to a particular year given that $Regulation_t$ dummies are multicollinear with the year fixed effects. $Regulation_t$ is our variable of interest that demonstrates whether the impact of the food allergen labeling regulation on food allergies is statistically different from its impact on the reference group diseases. $Regulation_t$ is represented by two different dummy variables: (i) $Voluntary_t$ that takes the value of one for all years after the industry guidelines went into effect in April 2001, and (ii) $Mandate_t$ that takes the value of one for all time periods after January 2006, when the federal mandate went into effect (Appendix 1.A).

In this setting C_{hst} in the first equation is regarded as an endogenous variable correlated with u_{hst} . Such an assumption may be rationalized in terms of the omitted unobserved characteristics of an OPD if it admits patients with food allergies and patients with control group diseases. A sequential two-step procedure estimates the first of the equations after replacing C_{hst} by an estimate of $E[C_{hst}|Regulation_{2t}, X_{2hst}, \delta_{2h}, \tau_{2t}, e_{hst}]$, which is uncorrelated with u_{hst} .

If the distribution of food allergies and control group diseases are of Poisson or Negative binomial type, and both models have multiplicative errors, then

$$A_{hst} = \exp(\alpha_1 * Regulation_{1t} + \alpha_2 * X_{1hst} + \alpha_3 * C_{1hst} + \alpha_4 * \delta_{1h} + \alpha_5 * \tau_{1t})v_{hst} \quad (1.3)$$

$$C_{hst} = \exp(\beta_1 * Regulation_{1t} + \beta_2 * X_{1hst} + \beta_3 * \delta_{1h} + \beta_4 * \tau_{1t})\epsilon_{hst} \quad (1.4)$$

where $v_{hst} = \exp(u_{hst})$ and $varepsilon_{hst} = \exp(e_{hst})$, and v_{hst} and ϵ_{hst} are *iid*, and the association between v_{hst} and ϵ_{hst} is characterized by $v = \epsilon + \eta$, where ϵ is normally and independently distributed. This amounts to an instrumental variable procedure (Cameron and Trivedi, 2013), where the set of excluded exogenous variables consists of higher powers of continuous variables including patients' age, the percent of a county population having a particular income and education, and higher powers of the time trend (Escanciano, Jacho-Chávez and Lewbel, 2010).

Given the distribution of food allergies and control group diseases, I exploit the negative binomial model with quadratic variance (NB2 model) and run separate regressions for voluntary and mandatory allergen disclosure. While evaluating the impact of the voluntary disclosure, enacted in April 2001, I focus only on the pre-mandate years of 1997 – 2005. While evaluating the federal mandate of 2006, I use all time periods. In this case, the "pre-regulation" period is 1997 – 2005, and the "post-regulation period" is 2006 – 2010. To account for a multi-stage probability design to sample certain PSUs, OPDs within PSUs, physician's practice within OPDs, I apply survey weights in all specifications. Survey weights correct for an endogenously varying probability to sample a

particular visit, which depends on characteristics not captured by the model. This includes patient's desire to seek medical help with a certain intensity of an allergic reaction, frequency of attending a particular doctor or a particular OPD etc. (CDC, 2012; Solon, Haider and Wooldridge, 2013).

My baseline specification outlined by equations (1.3) - (1.4) estimates the impact of an information campaign on food allergies controlling for the *fitted* number of patients with control group diagnoses, where the fitted values are based on OPD characteristics and patients' socio-economic and insurance characteristics averaged at an OPD level. Alternatively, I evaluate the policy controlling for the *observed* rather than fitted number of reference group diseases:

$$A_{hst} = \alpha_1 * Regulation_{1t} + \alpha_2 * X_{hst} + \alpha_3 * C_{hst} + \alpha_4 * \delta_h + \alpha_5 * \tau_t + e_{hst} \quad (1.5)$$

where C_{hst} represents the observed number of patients diagnosed with control group diseases per 10,000 OPD patients, documented in an OPD h at time period t , and the rest of the model is defined as before. This model serves as robustness check to the baseline specification. The primary specification is based on a restrictive assumption about multiplicative errors, and it uses an instrument variable procedure sensitive to a choice of optimal instruments. On the contrary, a model with observed control diseases is based on conventional additive errors, but it does not resolve an endogeneity of C_{hst} that might be correlated with e_{hst} . Therefore, utilization of both models substantiates validity of my results.

Results

Main Results

Characteristics of patients having food allergies are fairly stable over time (Table 1.2). These patients are mostly white, have private or Medicare/Medicaid insurance, and attending voluntary non-profit OPDs located predominantly in MSAs. The majority of patients visit a doctor

with non-acute allergies for their routine preventive care and periodic examinations, and about 35 percent patients have acute allergic reactions.

The only factor that substantially changes over time is patient age. In the pre-intervention period the mean age was about 33 years, while in the post-mandate period it has dropped to about 18. There are two possible reasons for this difference. First, the number of younger patients might increase over time. Second, the average age of a younger category might drop even though the ratio of the younger-to-older patients remains stable. To differentiate between these two effects, I split the sample into two categories: patients aged 15 and younger and those over 15. A "fifteen-year-old" threshold is based on epidemiological literature documenting that the majority of allergies develop under age 15 (Sicherer, 2011). The data supports the first hypothesis. The mean age of "adults" and "children" did not change substantially and varied around 50 – 52 and 2.6 – 3.9 years respectively⁶. At the same time, the number of patients under 15 increased more than five times during 1997 – 2010 (Table 1.1). This is consistent with the epidemiological literature, which provides several explanations to this phenomenon, including the shortening of the period of exclusive breastfeeding; the increasing use of antacids and antibiotics, resulting in exposure to more intact proteins; changes in food processing, such as switching to peanut roasting and emulsification compared to the use of fried or boiled peanuts etc. (Cochrane et al., 2009). The majority of these reasons, with the exception of exclusive breastfeeding, may also justify an increasing number of allergies among patients of both age categories (Table 1.1). However, most of the increase - 89 and 196 percent respectively - occurred after firms began disclosing allergens voluntarily. On the contrary, in the post-mandate period the number of allergies decreased by 27 percent for adults and by 7 percent for patients of both age categories. Furthermore, a year-to-year analysis of the trend (Figure 1.1) demonstrates that number of allergies have declined substantially in 2006 – 2009 - immediately

⁶Summary statistics for food allergies for patients of different age are available upon request.

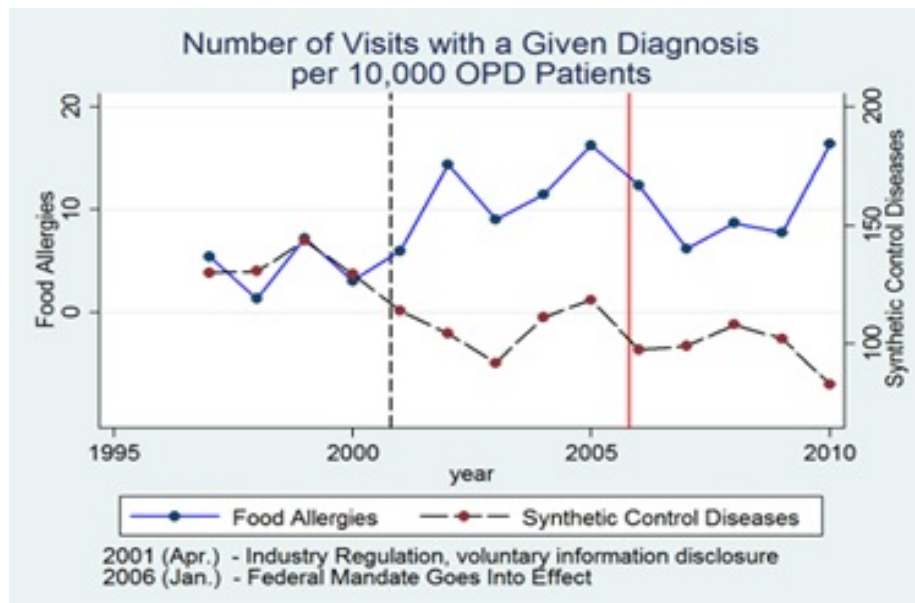
after the mandate was enacted - and increased to some extent four years later⁷.

In contrast to food allergies, the number of patients in both synthetic control groups does not change significantly over time. The number of patients with non-allergy control diseases, genetically unrelated to food allergies, fluctuates by only 6 – 8 percent. The number of patients in the non-food allergy control group changes by 14 – 37 percent (Table 1.2 columns 4 – 6 and 7 – 9 respectively). Since food and non-food allergies are triggered by the same genes, a 206 percent increase in food allergies might translate into a 30 percent raise in non-food allergies (given the same availability of anti-allergen medications). At the same time, the number of control group diseases per 10,000 OPD patients exhibited a slight decline over the course of 1997 – 2010, which is explained by a steady increase in the overall number of OPD patients over time.

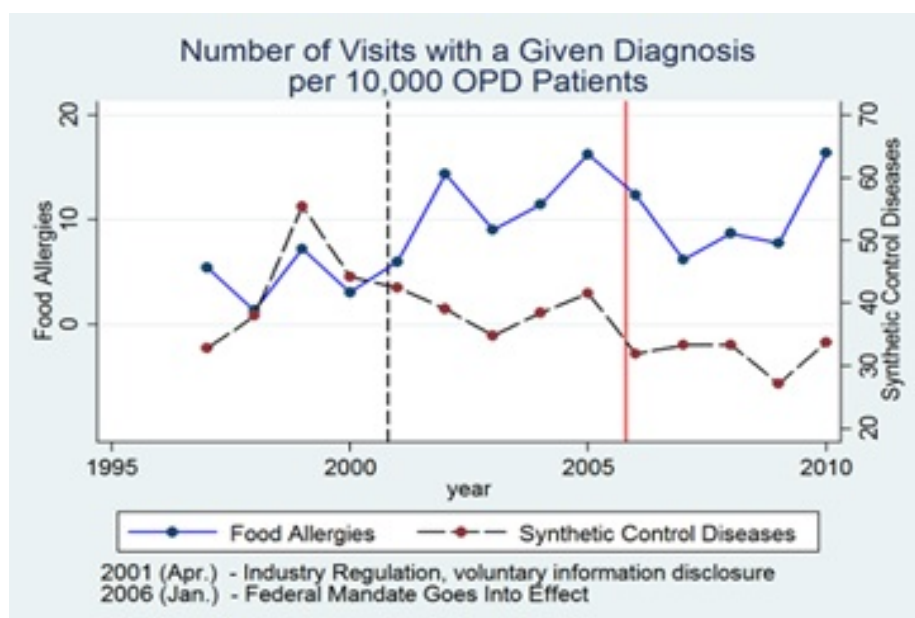
Primary results from NB2 estimation of equations 1.3 - 1.5 are reported in Table 1.3. Columns 1 – 8 demonstrate the results from our baseline specification, and columns 9 – 12 pertain to our robustness check specification outlined by equation 1.5. In my baseline model, odd columns report results of the *first* stage, while even columns show the estimates of the *second* stage, which is of major interest for this analysis. The first two columns of every specification (e.g. columns 5 – 6) demonstrate the impact of the voluntary information disclosure, while the last two columns (e.g. columns 7-8) pertain to the mandatory risks disclosure. In my robustness check specification, odd columns show the estimates for the voluntary disclosure, and even columns represent the mandatory disclosure. In this model, the coefficients for voluntary or mandatory disclosure pertain to food allergies only, and they are equivalent to the corresponding values from the second stage of the baseline specification (columns 2 and 6, and 4 and 8 respectively). The reported "control group diseases" in columns 9 – 12 are not interacted with the $Regulation_t$ variable. Therefore, they might

⁷The reasons behind a post-mandate increase in food allergies in the longer run are not well documented in epidemiological literature. Partially, it may be explained by an extensive use of an obscure "may contain (a specific allergen)" label statement, which is concluded to be "confusing and inconsistent" and "not providing adequate information to make smart and safe decisions" (FDA, 2008).

Figure 1.1: Food Allergies and Control Diseases over Time



(i) $\text{Synthetic Control} = 0.466 * \text{Bronchitis} + 0.31 * \text{Pneumonia} + 0.224 * \text{Skin Reactions}$



(ii) $\text{Synthetic Control} = 0.138 * \text{Allergic Asthma} + 0.862 * \text{Allergic Conjunctivitis}$

Since both voluntary and mandatory allergen disclosure affects the entire country, I compare food allergies to a synthetic control group represented by a weighted average of control diseases, with weights chosen so that the resulting synthetic "food allergies" best reproduce the values of a set of predictors of food allergy visits prior to 2001, when the first allergen labeling regulation went into effect. The set of predictors includes patient socio-economic characteristics including their race, gender, and age; patient insurance characteristics; and hospital characteristics including their location and ownership status. Synthetic Control Group (i) consists of non-allergy diagnoses, and it controls for unobserved advancements in medical technology targeting symptoms similar to food allergies. Synthetic Control Group (ii) consists of non-food allergies, and it controls for medical advancements in treating allergies. Source: NHAMCS outpatient department records and Census data for 1997-2010.

not be directly compared to coefficients from the first stage of our baseline specification (columns 1, 3, 5, and 7).⁸

Table 1.3 demonstrates that, regardless of the selected specifications or comparison groups, voluntary allergen labeling considerably *increased* the number of OPD visits with food allergies, while mandatory labeling led to a *decline* in food allergies. According to our results, after manufacturers disclosed allergens voluntarily, the number of OPD visits with food allergies increased 2.8 – 5.4 times depending on the fitted or actual control diseases (columns 2, 6, 9, and 11), while the number of control diseases per se slightly declined. At the same time, mandatory allergen warnings reduced food allergies by 25 – 40 percent, where the estimates from a robustness check specification are marginally significant at 14 – 16 percent (columns 4, 8, 10, and 12). Since the estimated effect of the allergen labeling campaigns is robust to the choice of the fitted or actual control group diagnoses, a two-step instrument variable procedure applied to a model with multiplicative errors provides consistent estimates of a policy effect. Remarkably, the estimated effect of the information campaigns is also robust to the choice of a synthetic control group. For instance, in the specifications controlling for non-allergy diagnoses and for non-food allergies, voluntary allergen disclosure led to a 4.0 and 5.4 time increase in OPD food allergy visits respectively. The estimates for mandatory disclosure are invariant to the choice of synthetic controls: both specifications show a 40 – 42 percent decrease in food allergy visits.

In Table 1.4 I also estimate an alternative specification in which I study the impact of the information campaigns on consumers of different age. This specification further corroborates my primary conclusion about the impact of voluntary and mandatory risks disclosure on consumer health. As for the age differences, patients aged 15 and younger are more affected by the voluntary

⁸I have additionally run a robustness check specification where control diseases were interacted with the Regulation variable. However, this didn't significantly change the estimates for food allergies, which are of the primary interest in this study. Therefore, for simplicity I report results from a more parsimonious specification.

Table 1.4: The Effect of Food Allergen Labeling Legislation for Different Age Categories, incidence ratios

	All Patients			Patients aged 15 and younger			Patients aged over 15					
	Controls, 1st step (1)	Allergies, 2nd step (2)	Controls, 1st step (3)	Allergies, 2nd step (4)	Controls, 1st step (5)	Allergies, 2nd step (6)	Controls, 1st step (7)	Allergies, 2nd step (8)	Controls, 1st step (9)	Allergies, 2nd step (10)	Controls, 1st step (11)	Allergies, 2nd step (12)
Voluntary Disclosure	0.825*** (0.049)	5.000*** (1.528)			0.700*** (0.068)	6.577*** (3.29)			0.800*** (0.061)	3.492*** (1.465)		
Mandatory Disclosure			0.829*** (0.056)	0.608*** (0.171)			0.839* (0.078)	1.450 (0.403)			0.848** (0.069)	0.316*** (0.126)
Number of OPDs	3,691	3,691	5,597	5,597	2,974	2,974	4,412	4,412	3,650	3,650	5,546	5,546

Note 1: See Table 1.3 notes. Synthetic Control (i) = 0.466 * Bronchitis + 0.31 * Pneumonia + 0.224 * Skin Reactions

Note 2: See Table 1.3 notes.

disclosure - a 5.6 time increase in OPD visits compared to a 2.5 time increase documented for an adult population. Similarly, older patients benefit more from the mandatory warnings: while the number of patients aged 15 and younger further increased by 45 percent, the number of older patients declined by 68 percent.

Multiple estimation techniques, based on different model specifications and different control groups, confirm the same conclusion: a voluntary disclosure of health risks is associated with a sizable increase in the number of vulnerable consumers seeking medical help, while mandatory disclosure steadily improves consumers' health. This result might be explained by a "learning" effect, assuming that customers need time to adjust to new information about product quality. Figure 1.1, complementing the results of our regressions, rules out this hypothesis, since the learning effect would be associated with a gradual rather than a "cave"-shaped decrease in food allergies after the allergens were voluntarily revealed to customers.

Our results seem to support an alternative hypothesis, which assumes that improvements in the health outcomes in the post-mandate period are explained by the uniform and compulsory warning display standards, which provide vulnerable consumers with the information sufficient to avoid risky products. On the contrary, deteriorating consumer health in the post-voluntary period signifies that consumers buy more risky products since they erroneously assume them to be safer. Erroneous consumers' expectations about product safety may stem from the non-uniform labeling standards or from the manufacturer's selection bias. The former presumes that less coordinated voluntary display standards may compromise consumers' ability to assign the proper amount of risk to a product. The latter implies that if consumers are not fully informed of the risks they face, firms may choose not to disclose information about the most dangerous ingredients. This hypothesis is supported by the prior empirical evidence. Mathios (2000) demonstrates that manufacturers voluntarily disclose information about all higher quality products. At the same time, they refrain

from notifying the public about lower-quality goods until this information is mandated. Similarly, Formanek (2001) documents that, prior to the food allergen labeling mandate, the FDA reported a significant number of unlabeled life-threatening allergens (e.g. peanuts), while allergens causing less severe reactions (e.g. milk, eggs etc.) were unlabeled rarely. This study does not allow clear differentiation between these two reasons. However, in the case of food allergen labeling, voluntary and mandatory standards for displaying allergen content were very similar. The only difference - banned fine prints and more clear requirements about positioning the warning on the labels - might explain some of the difference in the effect of voluntary and mandatory disclosures, but it is unlikely to result in a four-time increase in the demand for medical services in the post-voluntary period. Therefore, manufacturer's selective non-disclosure of more harmful ingredients seems to be a plausible hypothesis. Regardless of the reasons, the primary result of this study implies that mandatory disclosure of health risks provides the vulnerable consumers with the information sufficient to avoid risky products, while voluntary disclosure may adversely affect consumers' health.

Error in the Dependent Variable and Spillover Effects:

Impact of the Food Allergen Labeling on Non-food Allergies

The baseline specification analyzes the influence of the risks disclosure on food allergies that are directly affected by the legislation. However, according to epidemiological literature, food allergies are closely related to non-food allergies.

First, food and non-food allergies are triggered by the same genes. Therefore, one allergy type could serve as an augmentation factor exacerbating other allergies (Heratizadeh et al., 2011; Nowak-Wegrzyn et al., 2001; Venter et al., 2006). Table 1.5 summarizes the common cross-reactions between food allergies and their non-food associates. Cross-reaction implies that an increase in food allergies may result in a spillover rise in the corresponding non-food allergies.

Table 1.5: Common Cross - Reactions between Food and Non-food Allergies

Food Allergy	Non-Food Associate
1. Seafood	1. Mite allergy
2. Peanuts	2. Lupine pollen, ragweed pollen, atopic dermatitis/ eczema, atopic asthma
3. Almonds, hazel nuts, walnuts	3. Alder pollen, birch pollen; less common latex
4. Soy	4. Birch pollen
5. Cows milk and egg	5. Atopic dermatitis/ eczema; atopic asthma

Sources: Heratizadeh et al. (2011), Boyce et al (2010).

Second, doctors' ability to recognize food allergies is limited. According to epidemiological literature, physical exam tests, which are recognized as the gold standards for diagnosing allergies, confirm a positive diagnosis of food allergies in fewer than 50 percent of the cases diagnosed by a clinical history (Roberts, 2005). Moreover, physical exam tests are generally administered in hospitals or medical offices in order to reduce the risk of life-threatening reactions. Therefore, non-institutionalized medical practitioners might not be able to directly administer the tests and to make a clear diagnosis about the etymology of an allergy case (Niggemann et al., 2007). This may result in a measurement error in the dependent variable, since food allergies may be erroneously reported as non-food allergies.

To address the potential measurement error and spillover effects, I analyze the impact of the regulation on the full set of allergies, including food, non-food, and unspecified allergies. I compare all allergies to their synthetic control group consisting of skin reactions, rhinitis and sinusitis (Table 1.6). This synthetic control group corresponds to the composition of allergies, and it matches very closely the allergies in the pre-intervention period. Column 1 displays the full set of synthetic control predictors, including patients' socio-economic and insurance characteristics, as well as hospital characteristics.

I evaluate the impact of the voluntary and mandatory health warnings on allergies using a two-step multivariate framework defined by equations 1.3 - 1.4, where A_{hst} measures the number of

visits with any allergy rather than food allergies per 10,000 OPD patients. The rest of the model is designed as before.

Table 1.7 reports the results from NB2 estimation of this specification. Columns (1)-(4) outline the effect of the food allergen labeling on the full set of allergies, including food allergies, non-food allergies, and unspecified allergies. As a robustness check, I run a different regression where the outcome variable excludes food allergies. Since food allergies account for only 1 – 3 percent of all allergies (Table 1.5), the results of both specifications do not differ much. The odd columns report results of the first stage, while even columns show the estimates of the second stage, which is of major interest for this analysis.

According to our results, both voluntary and mandatory disclosure of the allergen content in foods does not significantly affect other allergy types. First, the corresponding coefficients in the even columns are statistically insignificant. Second, the magnitude of the incidence ratios does not differ much from the unity, which implies a zero percent change in the corresponding variables.

This result raises a couple of important conclusions. First, the probability of a measurement error in the dependent variable due to a "trigger effect" or a possibility of misdiagnosing food and non-food allergies is fairly low. Second, since the influence of a "trigger effect" is mild, non-food allergies with symptoms different from food allergies could serve as an adequate control group for food allergies in our baseline specification.⁹

Latent Demand for Medical Services

The major finding documented in the previous sections is that the voluntary disclosure of allergen content in food results in an increase in demand for OPD medical services, while the mandatory disclosure decreases the number of OPD allergy visits. However, my previous method-

⁹This is an "alternative control group", represented by Allergic Asthma and Allergic Conjunctivitis and reported in columns 13 - 15 of Table 1.2 and columns 5 - 8 and 11 - 12 of Table 1.4.

Table 1.6: All Allergies and their Synthetic Controls by Selected Characteristics, frequencies

	All Allergies			Control Group Diseases (iii)		
	A (1)	B (2)	C (3)	A (4)	B (5)	C (6)
Food Allergies	0.013	0.023	0.031			
Non-Food Allergies including	0.893	0.910	0.934			
Allergic Asthma and Bronchitis	0.528	0.520	0.545			
Allergic Rhinitis	0.278	0.311	0.302			
Allergic Skin Reactions	0.039	0.050	0.062			
Allergic Conjunctivitis	0.042	0.029	0.021			
Allergy to Drugs	0.031	0.033	0.040			
Allergic Purpura	0.002	0.001	0.001			
Allergic Pneumonitis and Alveolitis	0.000	0.000	0.001			
Allergy to Latex and Radiographic Dye	0.000	0.000	0.000			
Unspecified Allergies	0.102	0.075	0.048			
Urgency of Visit Composition						
Acute Reactions, including	0.527	0.535	0.526	0.772	0.813	0.767
Less informed patients (onset within three months of this visit)	0.400	0.423	0.411	0.690	0.733	0.708
More informed patients (three months and over)	0.128	0.112	0.115	0.082	0.079	0.059
Non-Acute Cases, More informed patients	0.455	0.465	0.474	0.208	0.187	0.233
Patients' Socio-Economic Characteristics						
Mean Patient's age, years	31.21 (0.83)	30.28 (0.97)	28.74 (1.22)	31.97 (0.54)	31.35 (0.81)	32.74 (0.98)
Patient Race: White	0.692	0.700	0.596	0.799	0.791	0.655
Patient Race: Black	0.271	0.258	0.252	0.178	0.176	0.164
Patient Race: Asian	0.032	0.022	0.020	0.019	0.019	0.013
Patient Sex: Female	0.603	0.602	0.596	0.599	0.625	0.603
Established Patient	0.867	0.886	0.884	0.782	0.848	0.828
Patients' Insurance Characteristics						
Private	0.424	0.427	0.443	0.494	0.507	0.506
Medicare	0.098	0.098	0.101	0.089	0.082	0.105
Medicaid	0.282	0.349	0.394	0.216	0.269	0.301
Worker's Compensation	0.003	0.002	0.002	0.002	0.002	0.001
Self-Pay	0.070	0.051	0.059	0.110	0.080	0.086
No Charge	0.025	0.019	0.022	0.012	0.01	0.018
Other	0.052	0.027	0.037	0.050	0.032	0.038
OPD Characteristics						
MSA area	0.823	0.772	0.792	0.776	0.696	0.768
Location: Northeast	0.246	0.257	0.244	0.181	0.152	0.146
Location: Midwest	0.290	0.288	0.321	0.327	0.361	0.410
Location: South	0.324	0.338	0.339	0.346	0.362	0.324
Ownership: Voluntary non-profit	0.676	0.782	0.765	0.734	0.810	0.773
Ownership: Govern., non-Federal	0.273	0.208	0.221	0.199	0.175	0.213
Ownership: Proprietary	0.051	0.011	0.014	0.067	0.015	0.014

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	All Allergies			Control Group Diseases (iii)		
	A (1)	B (2)	C (3)	A (4)	B (5)	C (6)
Census Variables (OPDs county), means						
BA degree	25.29 (1.09)	25.52 (1.11)	27.42 (0.97)	23.66 (0.94)	24.40 (0.97)	26.92 (0.83)
Do not speak English	16.82 (0.99)	16.77 (1.12)	15.29 (0.86)	13.04 (0.92)	12.91 (0.81)	12.78 (0.75)
Foreign born	10.75 (0.67)	11.08 (0.82)	10.11 (0.61)	7.91 (0.57)	8.19 (0.54)	8.58 (0.54)
Household income, ths USD	24.12 (0.41)	22.39 (0.38)	22.59 (0.44)	24.11 (0.46)	22.50 (0.47)	22.74 (0.47)
Below poverty	13.68 (0.46)	14.48 (0.31)	15.90 (0.32)	12.83 (0.48)	13.67 (0.35)	15.14 (0.39)
Number of cases, thousand patients	15275.6	20720.7	18950.4	17056.5	19741.9	19507.7
Number of cases per 10,000	37.46	39.79	32.71	18.40	16.93	15.38

Columns: A - pre-regulation period (1997-2000); B - voluntary risk information disclosure (2001-2005); C - mandatory risk information disclosure (2006-2010). Data Source: NHAMCS outpatient department records and Census data for 1997-2010.

Since both voluntary and mandatory allergen disclosure affects the entire country, I compare allergies to a synthetic control group represented by a weighted average of non-allergy diagnoses, with weights chosen so that the resulting synthetic "allergies" best reproduce the values of a set of predictors of allergy visits prior to 2001, when the first allergen labeling regulation went into effect. The set of predictors includes patient socio-economic characteristics including their race, gender, and age; patient insurance characteristics; and hospital characteristics including their location and ownership status. Synthetic Control Group controls for unobserved advancements in medical technology targeting symptoms similar to allergies.

Synthetic Control (iii)=0.626*Skin Reactions+0.374*Rhinitis and Sinusitis.

ology does not allow for identifying whether the regulation changes the number of OPD allergy patients while the total number of people who suffer from allergies remains unaffected, or if the change in OPD visits reflects the change in the number of consumers who have experienced allergic reactions in the post-regulation period.

I now seek to answer these questions. By doing so, first I indirectly control for the change in the number of patients who have experienced allergic reactions even if some of them were not recorded in an OPD. Second, I use the endogenous stratification technique to estimate the latent need for medical services among consumers with food allergies.

I account for the unobserved change in allergic reactions, including reported and unreported

Table 1.7: Impact of Food Allergen Content Disclosure on All Allergies and Non-Food Allergies, incidence ratios

	All Allergies				Non-Food Allergies Only			
	Controls, 1st step (1)	Allergies, 2nd step (2)	Controls, 1st step (3)	Allergies, 2nd step (4)	Controls, 1st step (5)	Allergies, 2nd step (6)	Controls, 1st step (7)	Allergies, 2nd step (8)
Voluntary Disclosure	0.909* (0.047)	0.982 (0.062)			0.909* (0.048)	0.982 (0.065)		
Mandatory Disclosure			0.863 (0.083)	0.964 (0.078)			0.863 (0.083)	0.996 (0.086)
Number of OPDs	3691	3691	5597	5597	3691	3691	5597	5597

Note 1: Since both voluntary and mandatory allergen disclosure affects the entire country, I compare allergies to a synthetic control group represented by a weighted average of non-allergy diagnoses, with weights chosen so that the resulting synthetic "allergies" best reproduce the values of a set of predictors of allergy visits prior to 2001, when the first allergen labeling regulation went into effect. The set of predictors includes patient socio-economic characteristics including their race, gender, and age; patient insurance characteristics; and hospital characteristics including their location and ownership status. Synthetic Control Group controls for unobserved advancements in medical technology targeting symptoms similar to allergies. Synthetic Control (iii)=0.626*Skin Reactions+0.374*Rhinitis and Sinusitis.

Note 2: In all regressions, while not reported, I also include the following controls: (i) patients' socio-economic characteristics including their race, gender, and "established patient" status, (ii) patients insurance characteristics, (iii) Census records on education, income, and English literacy reported for an OPD county, (iv) state fixed effects, polynomial year time trend, months fixed effects (definitions of the variables are provided in Appendix A). The 1st stage for a multivariate 2-step procedure (estimating number of visits with control group diseases) is presented in odd columns, and the 2nd step (estimating food allergies given fitted control group diseases) is reported in even columns. Stars denote significance levels: 99 percent confidence level (***), 95 percent confidence level (**), and 90 percent confidence level (*). Data Source: NHAMCS outpatient department records and Census data for 1997-2010.

Note 3: "All allergies" include food and non-food allergies.

cases, by comparing more informed to less informed patients¹⁰ diagnosed with food allergies. Both groups are similarly affected by the overall change in the number of allergic reactions. At the same time, more informed patients, who have been living with their disease for longer, have more information about their disease, and thus they are likely to benefit the most from the allergy warnings on food labels. This method is based on an assumption that during a survey period more and less informed consumers are equally likely to seek medical help. Given that each NHAMCS medical practitioner is surveyed during one week only (CDC, 2012a), this assumption seems to be plausible.

I use a two-step multivariate estimation framework defined by equations 1.3 - 1.4. In this setting the first step evaluates less informed patients, controlling for the number of the reference

¹⁰The definition of the more and less informed patients is provided in Appendix 1.A.

group diseases, and the second step focuses on more informed patients, controlling for the number of the less informed patients estimated from the first step and the number of the reference group diseases. In the former case, patients with the reference group diseases include only "less informed" individuals, while in the latter case we control for both "less" and "more informed" reference group patients. Table 1.8 reports the estimated incidence ratios from the above specification. The estimated coefficients for the voluntary information disclosure are all positive and statistically significant, indicating an overall 5.2 – 5.7 time increase in the number of OPD visits with food allergies for the less and more informed patients respectively. This indicates that even after controlling for the overall change in the number of allergic reactions, the voluntary display of health warnings fails to provide more informed customers with sufficient information about the quality of products. On the contrary, the mandatory information disclosure is more efficient in improving health outcomes of the vulnerable consumers. The number of less informed patients - those diagnosed with their allergies within the last three months - increased even further. At the same time, the number of more informed patients is reported to decline by 42 percent, and this coefficient is marginally significant at 14 percent. This indicates that, regardless of the change in the number of allergic reactions undocumented in OPDs, mandatory health warnings are associated with a substantial decrease in the number of well-informed vulnerable consumers seeking medical help.

Next, I intend to measure the effect of the voluntary and mandatory regulation on the latent demand for medical services among all consumers who might experience allergic reactions. By doing so, I exploit the endogenous stratification technique designed to correct for the sample truncation resulting from the fact that only those patients who use the facility at least once are included in the survey. Furthermore, even among users, the likelihood of being included in the sample depends on the frequency of use, which results in endogenous sampling (Cameron and Trivedi, 2013; Hilbe, 2011). The density function suitable for analyzing on-site samples needs to account for the

Table 1.8: **Impact of the Legislation on Food Allergies Controlling for the Change in the Total Number of Allergic Reactions, incidence ratios**

	Initial Specification: Food Allergies vs Control Group				More Informed versus Less Informed Patients with Food Allergies			
	Controls, 1st step (1)	Allergies, 2nd step (2)	Controls, 1st step (3)	Allergies, 2nd step (4)	Controls, 1st step (5)	Allergies, 2nd step (6)	Controls, 1st step (7)	Allergies, 2nd step (8)
Voluntary Disclosure	0.825*** (0.049)	5.000*** (1.528)			6.201*** (2.534)	6.747*** (2.862)		
Mandatory Disclosure			0.826*** (0.056)	0.608*** (0.171)			4.706* (2.240)	0.583 (0.213)
Number of OPDs	3,690	3,690	5,595	5,595	3,690	3,690	5,595	5,595

Note 1: Since both voluntary and mandatory allergen disclosure affects the entire country, I compare food allergies to a synthetic control group represented by a weighted average of non-allergy diagnoses, with weights chosen so that the resulting synthetic "food allergies" best reproduce the values of a set of predictors of food allergy visits prior to 2001, when the first allergen labeling regulation went into effect. The set of predictors includes patient socio-economic characteristics including their race, gender, and age; patient insurance characteristics; and hospital characteristics including their location and ownership status. Synthetic Control Group controls for unobserved advancements in medical technology targeting symptoms similar to food allergies. Synthetic Control=0.466*Bronchitis+0.31*Pneumonia+0.224*Skin Reactions.

Note 2: In all regressions, while not reported, I also include the following controls: (i) patients' socio-economic characteristics including their race, gender, and "established patient" status, (ii) patients insurance characteristics, (iii) Census records on education, income, and English literacy reported for an OPD county, (iv) state fixed effects, polynomial year time trend, months fixed effects (definitions of the variables of the variables are provided in Appendix A). The 1st stage for a multivariate 2-step procedure is presented in odd columns, and the 2nd step is reported in even columns. Columns (1)-(8) compare less and more informed patients, diagnosed with food allergies, to their control diseases; columns (9)-(12) compare less informed to more informed patients diagnosed with food allergies. Stars denote significance levels: 99 percent confidence level (***), 95 percent confidence level (**), and 90 percent confidence level (*). Data Source: NHAMCS outpatient department records and Census data for 1997-2010.

joint effect of truncation and stratification. Cameron and Trivedi (2013) and Englin and Shonkwiler (1995) have shown that for a special case of Poisson and Negative binomial regressions the population conditional density can be retrieved from the conditional density of the endogenously stratified sample. Specifically, according to (Cameron and Trivedi, 2013), the population density for $P[\mu_i]$ is

$$g^s(y_i|\mu_i) = \frac{e^{-\mu_i} \mu_i^{y_i-1}}{(y_i - 1)!}$$

For the negative binomial with quadratic variance (Englin and Shonkwiler, 1995), it is

$$h^s(y_i|\mu_i) = \frac{y_i \Gamma(y_i + \frac{1}{\alpha_i}) \alpha_i^{y_i} \mu_i^{y_i-1} (1 + \alpha_i \mu_i)^{-(y_i + \frac{1}{\alpha_i})}}{\Gamma(y_i + 1) \Gamma(\frac{1}{\alpha_i})}$$

Table 1.9: Impact of the Legislation on the Latent Demand for Medical Services among Consumers with Food Allergies, incidence ratios

	Initial Specification				Model with Endogenous Stratification			
	Controls, 1st step (1)	Allergies, 2nd step (2)	Controls, 1st step (3)	Allergies, 2nd step (4)	Controls, 1st step (5)	Allergies, 2nd step (6)	Controls, 1st step (7)	Allergies, 2nd step (8)
Voluntary Disclosure	0.825*** (0.049)	5.000*** (1.528)			0.822*** (0.049)	5.056*** (1.555)		
Mandatory Disclosure			0.826*** (0.056)	0.608*** (0.171)			0.825* (0.056)	0.608* (0.174)
No of OPDs	3,690	3,690	5,595	5,595	3,690	3,690	5,595	5,595
Estimated Number of Patients with Allergies per 10,000 OPD Patients, E[Yi—Xi]		(Voluntary)	(Mandatory)		(Voluntary)	(Mandatory)		
<i>Prior to the Regulation</i>		4.57	5.92		4.62	5.99		
<i>After the Regulation</i>		6.74	5.97		6.81	6.04		

Note 1: See Table 1.8 notes. Synthetic Control=0.466*Bronchitis+0.31*Pneumonia+0.224*Skin Reactions.

Note 2: In all regressions, while not reported, I also include the following controls: (i) patients' socio-economic characteristics including their race, gender, and "established patient" status, (ii) patients insurance characteristics, (iii) Census records on education, income, and English literacy reported for an OPD county, (iv) state fixed effects, polynomial year time trend, months fixed effects (definitions of the variables are provided in Appendix A). The 1st stage for a multivariate 2-step procedure (estimating number of visits with control group diseases) is presented in odd columns, and the 2nd step (estimating food allergies given fitted control group diseases) is reported in even columns. Stars denote significance levels: 99 percent confidence level (***), 95 percent confidence level (**), and 90 percent confidence level (*). Data Source: NHAMCS outpatient department records and Census data for 1997-2010.

The moment conditions for population conditional density are defined as

$$E[y_i|x_i] = \mu_i + 1$$

$$V[y_i|x_i] = \mu_i$$

for Poisson regression (Cameron and Trivedi, 2013) and

$$E[y_i|x_i] = \mu_i + 1 + \alpha_i \mu_i$$

$$V[y_i|x_i] = \mu_i (1 + \alpha_i + \alpha_i \mu_i + \alpha_i^2 \mu_i)$$

for negative binomial regression (Cameron and Trivedi, 2013; Englin and Shonkwiler, 1995), where α_i is a dispersion parameter.

Given the population density functions, the Poisson population mean parameter can be

consistently estimated by making the transformation $w_i = y_i - 1$ and thus by applying the Poisson model to the original data with one subtracted from all y observations. Negative binomial model requires parametrization of α_i . Following Cameron and Trivedi (2013), Englin and Shonkwiler (1995), and Hilbe (2011), I define α_i as $\alpha_i = \alpha_0/\mu_i$.

The estimation is based on the two-step multivariate procedure outlined by equations 1.3 - 1.4, where A_{hst} and C_{hst} define food allergies and the control group respectively, and the rest of the specification is set as before. The results from this specification are reported in Table 1.9.

According to our results, the impact of voluntary and mandatory information disclosure on the latent demand for OPD medical services is similar to its impact on food allergies recorded in OPDs. For instance, the estimated effect of the voluntary disclosure on the latent demand is only 5 percent higher compared to the registered demand, and the estimated effect of the mandatory warnings is reported to be the same in both specifications. The estimated average number of allergic patients per 10,000 OPD patients $E[Y_i|X_i]$, computed for the baseline specification and the model with the endogenous stratification, demonstrates the same trend. These estimates further reinforce the primary conclusion of this paper: the need for the medical services increases by about four times after the voluntary disclosure of the health risks, and it declines by forty percent in the post-mandate period.

Discussion and Conclusions

This paper analyzes the risk information campaigns familiarizing consumers with hazardous attributes of products and compares industry initiatives, advocating voluntary information disclosure, to labeling mandates set by the government. The efficacy of the risk information campaign is assessed on an example of food allergen labeling regulation that stresses the need to list on food labels the major allergens responsible for 90 percent of all food allergies. Both voluntary and

mandatory allergen labeling set similar display standards designed to make the allergy warning clear and easy to comprehend. Additionally, the federal mandate banned fine prints and sets a uniform standard for positioning allergens on food labels and thus made the warnings more noticeable for consumers.

I evaluate the voluntary and mandatory allergen content disclosure by looking at their impact on the utilization of medical services by vulnerable consumers. The central finding is that the voluntary display of the risk information is associated with a sizable increase in the demand for medical services, while mandatory warnings result in a steady decline in the number of allergic patients seeking medical help. As for the voluntary display of the allergy warnings, the number of patients diagnosed with allergies has increased on average as much as four times compared to the pre-regulation period. Since the magnitude of the effect was unexpectedly high, I additionally looked at consumers of different age groups, compared patients with food allergies to different synthetic control groups, and evaluated the change in the latent demand for medical services among allergic consumers. Eventually, I concluded that my result is robust to the model specification changes.

These results raise a couple of interesting conclusions. First, they demonstrate that the effects of information campaigns familiarizing consumers with favorable and harmful attributes of goods are very different. According to the previous literature, the display of favorable product characteristics either benefits consumers if the message is clear enough or does not change their behavior if customers experience information overload. On the contrary, the disclosure of products' risk characteristics might adversely affect consumers' health if the disclosure policy is not chosen carefully. Second, consequences of the voluntary and mandatory disclosure of the risk information might differ substantially. As this study shows, the voluntary display of harmful ingredients might result in deteriorating consumers' health, while the mandatory disclosure suppresses the need for

medical services among the vulnerable customers.

The existing theoretical literature allows for several explanations of these phenomena. First, voluntary information disclosure might allow for less coordinated warning display standards. This may affect consumers' ability to locate and comprehend the message. On the contrary, the mandatory disclosure sets uniform standards for positioning and wording of the message, which makes the warning more noticeable and clear. Second, under voluntary disclosure, if consumers are numerous and not fully informed of the risks they face, some producers may refrain from revealing information about lower quality products, such as products with a higher content of harmful ingredients or products containing the most dangerous ingredients, and consumers may erroneously consider the products without warnings to be safer. On the contrary, mandatory information disclosure does not allow for manufacturers' selection bias. Therefore, it might serve as a better tool to satisfy the market demand for quality information.

This study does not allow clear differentiation between these two reasons. It is important to notice, however, that in the case of food allergen labeling regulation, the voluntary and mandatory scenarios set very similar criteria about clarity of the warnings. The only difference - banned fine prints and more clear standards about positioning the warning on the labels, set by the labeling mandate - might explain some of the difference in the effect of the voluntary and mandatory warnings, but it is unlikely to result in a four-time increase in the demand for medical services in the post-voluntary period. Thus, the manufacturers' selection bias seems to be a more plausible explanation. Yet, any affirmative conclusion about the reasons that cause the difference in the impact of both policies requires further analysis.

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Appendix 1.A: Definition of the variables

OUTCOME VARIABLES:

Number of Visits - Number of patients with food allergies or control group diseases per 10,000

OPD patients. A visit is defined as food allergies or control group disease if any of the three physician's diagnoses contain corresponding ICD-9 disease codes.

Urgency of Visits (Based on the "major reason for patient's visit" (MRV) variable. Since MRV contains only one reason for the current visit, the classification of allergy intensity types does not overlap)

- *Acute recent case (less informed patients)* - Dummy variable that takes the value of one if MRV is indicated as a "visit for a condition, illness, or injury having a relatively sudden or recent onset (within three months of this visit)".
- *Acute pre-existing case (more informed patients)* - Dummy variable that takes the value of one if MRV is indicated as a "a visit primarily due to sudden exacerbation of a pre-existing chronic condition".
- *Non-acute cases (more informed patients)* - Dummy variable equals to one if MRCV is indicated as one of the following options: (i) "chronic routine problem (a visit primarily to receive care or examination for a pre-existing chronic condition, illness, or injury (onset of condition was three months or more before this visit)", (ii) "pre- or post- surgery (e.g., pre-surgery tests, removing sutures)", or (iii) "preventive care general medical examinations and routine periodic examinations (including annual physicals, screening, and insurance)".

CONTROL VARIABLES:

Food allergen labeling regulatory initiatives including

- *Voluntary Disclosure* - Dummy variable indicating the period after the Industry guidelines went into effect (April 2001).
- *Federal mandate* - Dummy variable that equals one for all time periods after January 2006 when the Federal mandate went into effect.

Patients' Socio-Economic Characteristics

Mean Patient's age, years - Urgency of visits regression: Patient age in years. Number of visits regression: Mean patients' age in years.

Patient Race; includes dummies for White, Black, Asians, and patients of other races - Urgency of visits regression: dummy variable indicating if a patient is of particular race (e.g. Asian). Number of visits regression: average number of patients of a certain race in an OPD.

Patient Sex: Female - Urgency of visits regression: dummy variable indicating if a patient is a female. Number of visits regression: average number of female patients in an OPD.

Established Patient (Based on SENBEFOR dummy variable indicating if any medical practitioner in an OPD has seen a patient before) - Urgency of visits regression: dummy variable indicating if a patient was ever seen by an OPD practitioner before. Number of visits regression: average number of the corresponding patients in an OPD.

Patients' Insurance Characteristics (Based on PAYTYPE variable reporting primary expected source of payment for the current visit)

Private - Dummy variable equals to one if PAYTYPE =1; includes Blue Cross, commercial carriers,

and private HMOs and PPOs.

Medicare and Medicaid - Dummy variable equals to one if PAYTYPE=2 or PAYTYPE=3 respectively; includes both fee-for-service and managed care Medicare/ Medicaid/SCHIP patients.

Worker's Compensation, Self-Pay, No Charge, Other - Dummy variable equals to one if PAYTYPE =4, PAYTYPE =5, PAYTYPE =6, or PAYTYPE =7 respectively.

OPD Characteristics

MSA area - Dummy variable indicating if a visit occurred in MSA location.

Location; includes dummies of Northeast, Midwest, and South - Dummy variable indicating if an OPD is located in a certain Census region.

Hospital Ownership - Reflects the primary owner of the hospital based on the Verispan Hospital Data Base. It is represented by OWNSMG variable in 1997-1999 and by OWNER variable in 2000-2010, including

- *Voluntary non-profit* - Dummy variable equals to one if an OPD belongs to "Voluntary non-profit" group including hospitals that are (i) church-related, (ii) referred to a nonprofit corporation, or (iii) have other nonprofit ownership.
- *Government, non-Federal* - Dummy variable indicating if an OPD belongs to the "Government, non-Federal" group including hospitals that are operated by State, county, city, city-county, or hospital district or authority.
- *Proprietary* - Dummy variable equals to one if an OPD belongs to "Proprietary" group including hospitals that are (i) individually or privately owned or (ii) are partnerships or corporations for profit.

Census Variables

BA degree - Percent of population in OPD's county (or in patient's ZIP code of residence) with BA or higher.

Do not speak English - Percent of population in OPD's county (or in patient's ZIP) that do not speak English at all or very well.

Foreign born - Percent of population in OPD's county (or in patient's ZIP) that are foreign born.

Household income, ths USD - Median household income in OPD's county (or in patient's ZIP code of residence).

Below poverty - Percent pop below poverty level in OPD's county (or in patient's ZIP).

Appendix 1.B: ICD-9-CM diagnoses coding**Food allergies:**

477.1 - Allergic rhinitis due to food

558.3 - Allergic gastroenteritis and colitis

692.5 - Contact dermatitis and other eczema due to food in contact with skin

693.1 - Dermatitis due to food

995.6 - Anaphylactic shock due to adverse food reactions

995.7 - Other adverse food allergic reactions not elsewhere specified

988 - Toxic effect of mushrooms, berries, fish and shellfish etc.

V15.01 - Allergy to peanuts

V15.02 - Allergy to milk products

V15.03 - Allergy to eggs

V15.04 - Allergy to seafood

V15.05 - Allergy to other foods and food additives

Non-Food allergies:

Having symptoms common in food allergies:

Asthma and Bronchitis:

493.0 - Extrinsic asthma

493.9 - Bronchial allergic non-specified asthma

Skin Reactions:

691.8 - Other atopic (allergic) dermatitis

692.8 - Dermatitis due to cosmetics, metals and jewelry, animal hair

708.0 - Allergic urticarial (hives)

Allergy to drugs:

525.66 - Allergy to existing dental restorative materials

995.0 - Allergy to drugs and medical substances

995.2 - Unspecified adverse reaction to drugs taken internally (including correct and unspecified medical substances)

V14 - Allergy to medicinal agents

V64.04 - Allergy to vaccine and components

Having symptoms rare in food allergies:

Alveolitis and pneumonitis:

495 - Extrinsic allergic alveolitis and pneumonitis

Rhinitis:

477.0 - Allergic rhinitis due to pollen

477.2 - Allergic rhinitis due to animal hair and danger

477.8 - Allergic rhinitis due to other allergen

477.9 - Allergic rhinitis unspecified

Other allergies:

287.0 - Allergic purpura

372.05 - Acute atopic conjunctivitis

372.14 - Chronic allergic conjunctivitis

495 - Extrinsic allergic alveolitis and pneumonitis due to inhaled organic dust particles

V15.06 - Allergy to insects (including insect sting allergy and allergy to insects' protein)

V15.07 - Allergy to latex (results from inhaling or direct skin contact to latex proteins)

V15.08 - Allergy to radiographic dye

Unspecified Allergies:

995.3 - Allergy, unspecified

V15.09 - Other allergy, other than to medicinal agents

Control non-allergy diagnoses:

Respiratory system:

Asthma:

493.1 - Intrinsic asthma

493.2 - Chronic obstructive asthma

493.8 - Other forms of asthma

Bronchitis:

466 - Acute bronchitis and bronchiolitis

490 - Bronchitis, not specified as acute or chronic

491 - Chronic bronchitis

494 - Bronchiectasis

Pneumonia:

480 - Viral pneumonia

481 - Pneumococcal pneumonia (Streptococcus pneumonia)

482 - Other bacterial pneumonia

483 - Pneumonia due to other specified organism

484 - Pneumonia in infectious diseases classified elsewhere

485 - Bronchopneumonia, organism unspecified

486 - Pneumonia, organism unspecified

Rhinitis and Sinusitis:

472.0 - Chronic rhinitis (excluding allergic rhinitis)

473 - Chronic sinusitis

461 - Acute sinusitis

Pharyngitis:

472.1 - Chronic pharyngitis

472.2 - Chronic nasopharyngitis

460 - Acute nasopharyngitis (common cold)

462 - Acute pharyngitis including infective and bacterial cases

Tonsillitis:

463 - Acute tonsillitis including infective and bacterial cases

474 - Chronic disease of tonsils and adenoids

Skin Reactions:

Dermatitis:

691.0 - 691.7 - Non-Allergic Dermatitis

692.0 - 692.4, 692.6-692.9 - Non-Allergic Contact Dermatitis

693 - Dermatitis

Other Skin Reactions:

708.1 - 708.9 - Non-allergic urticaria

110 - Dermatophytosis

054 - Herpes simplex

Other Diseases:

372.00 - 372.04, 372.10- 372.13, 372.15, 372.2 - 372.9 - Non-allergic conjunctivitis

316 - Psychic factors associated with diseases classified elsewhere including psychogenic asthma, dermatitis, eczema, urticaria

Appendix 1.C: Selected Results

Table 1.10: Food Allergies and their Synthetic Controls by Census Characteristics, means

	Food Allergies			Control Group Diseases (i): Non-Allergy Cases			Control Group Diseases (ii): Non-Food Allergies		
	A (1)	B (2)	C (3)	A (4)	B (5)	C (6)	A (7)	B (8)	C (9)
Census Variables (OPDs county)									
BA degree	24.46 (1.99)	27.36 (1.18)	29.38 (0.97)	23.44 (0.82)	25.19 (0.93)	27.26 (0.89)	26.37 (1.05)	27.11 (0.81)	28.55 (0.99)
Do not speak English	14.00 (1.56)	18.28 (1.61)	14.96 (2.25)	14.10 (0.95)	13.75 (0.81)	13.73 (0.77)	19.32 (1.02)	19.08 (1.06)	16.44 (1.01)
Foreign born	8.61 (0.64)	11.97 (1.19)	9.68 (1.41)	8.70 (0.6)	8.91 (0.57)	9.19 (0.55)	12.47 (0.71)	12.73 (0.76)	10.83 (0.69)
Household income, ths USD	23.98 (0.79)	23.25 (0.49)	23.27 (1.09)	24.19 (4.45)	22.77 (4.78)	23.03 (4.74)	24.36 (4.56)	22.79 (3.99)	23.01 (4.82)
Below poverty	12.55 (0.65)	14.38 (0.45)	15.82 (0.82)	12.95 (0.45)	13.56 (0.33)	14.98 (0.35)	14.16 (0.48)	14.69 (0.36)	15.78 (0.37)
Census Variables (Patients ZIP)									
BA degree	NA	22.78 (2.17)	22.73 (1.51)	NA	21.62 (0.86)	21.41 (0.82)	NA	20.65 (0.62)	20.88 (0.68)
Do not speak English	NA	4.87 (0.76)	3.89 (0.77)	NA	3.17 (0.21)	3.19 (0.22)	NA	5.06 (0.42)	4.12 (0.31)
Foreign born	NA	12.90 (1.89)	9.79 (1.99)	NA	8.61 (0.52)	8.62 (0.51)	NA	12.46 (0.82)	10.53 (0.71)
Household income, ths USD	NA	78.93 (21.63)	47.35 (4.11)	NA	80.92 (5.51)	53.27 (4.81)	NA	83.41 (6.45)	50.10 (4.89)
Number of cases, thousand patients	173.1	473.6	635.9	16664	18020	16967	8463.7	11700	10365
Number of cases per 10,000 OPD patients	4.28	11.25	10.50	133.4	107.5	97.5	42.5	39.3	31.9

Columns: A - pre-regulation period (1997-2000); B - voluntary risk information disclosure (2001-2005); C - mandatory risk information disclosure (2006-2010). Data Source: NHAMCS outpatient department records and Census data for 1997-2010.

Since both voluntary and mandatory allergen disclosure affects the entire country, I compare food allergies to a synthetic control group represented by a weighted average of control diseases, with weights chosen so that the resulting synthetic "food allergies" best reproduce the values of a set of predictors of food allergy visits prior to 2001, when the first allergen labeling regulation went into effect. The set of predictors includes patient socio-economic and insurance characteristics and hospital characteristics. Synthetic Control Group (i) consists of non-allergy diagnoses, and it controls for unobserved advancements in medical technology targeting symptoms similar to food allergies. Synthetic Control Group (ii) consists of non-food allergies, and it controls for medical advancements in treating allergies.

(i) Synthetic Control=0.466*Bronchitis+0.31*Pneumonia+0.224*Skin Reactions;

(ii) Synthetic Control=0.138*Allergic Asthma+0.862*Allergic Conjunctivitis

Table 1.11: All Allergies and their Synthetic Controls by Census Characteristics, means

	All Allergies			Control Group Diseases (iii)		
	A (1)	B (2)	C (3)	A (4)	B (5)	C (6)
Census Variables (OPDs county)						
BA degree	25.29 (1.09)	25.52 (1.11)	27.42 (0.97)	23.66 (0.94)	24.40 (0.97)	26.92 (0.83)
Do not speak English	16.82 (0.99)	16.77 (1.12)	15.29 (0.86)	13.04 (0.92)	12.91 (0.81)	12.78 (0.75)
Foreign born	10.75 (0.67)	11.08 (0.82)	10.11 (0.61)	7.91 (0.57)	8.19 (0.54)	8.58 (0.54)
Household income, ths USD	24.12 (0.41)	22.39 (0.38)	22.59 (0.44)	24.11 (0.46)	22.50 (0.47)	22.74 (0.47)
Below poverty	13.68 (0.46)	14.48 (0.31)	15.90 (0.32)	12.83 (0.48)	13.67 (0.35)	15.14 (0.39)
Census Variables (Patients ZIP)						
BA degree	NA	20.45 (0.82)	20.49 (0.67)	NA	20.96 (0.84)	21.03 (0.78)
Do not speak English	NA	4.37 (0.39)	3.66 (0.25)	NA	3.01 (0.23)	3.05 (0.23)
Foreign born	NA	11.07 (0.87)	9.59 (0.58)	NA	8.14 (0.55)	8.07 (0.53)
Household income, ths USD	NA	81.39 (5.51)	48.84 (4.00)	NA	78.09 (7.00)	51.19 (3.09)
Number of Cases	15275658	20720713	18950399	17056529	19741858	19507673
Number of cases per 10,000 OPD patients	37.46	39.79	32.71	18.40	16.93	15.38

Columns: A - pre-regulation period (1997-2000); B - voluntary risk information disclosure (2001-2005); C - mandatory risk information disclosure (2006-2010). Data Source: NHAMCS outpatient department records and Census data for 1997-2010.

Since both voluntary and mandatory allergen disclosure affects the entire country, I compare allergies to a synthetic control group represented by a weighted average of non-allergy diagnoses, with weights chosen so that the resulting synthetic "allergies" best reproduce the values of a set of predictors of allergy visits prior to 2001, when the first allergen labeling regulation went into effect. The set of predictors includes patient socio-economic characteristics including their race, gender, and age; patient insurance characteristics; and hospital characteristics including their location and ownership status. Synthetic Control Group controls for unobserved advancements in medical technology targeting symptoms similar to allergies.

Synthetic Control (iii)=0.626*Skin Reactions+0.374*Rhinitis and Sinusitis.

Table 1.12: All Allergies and their Synthetic Controls by Census Characteristics, means

	Non-Urgent Cases (1)	Non- Urgent Cases (2)	Urgent Cases, Total (3)	Urgent Cases, Total (4)	Urgent Recent Cases (5)	Urgent Recent Cases (6)	Urgent Pre-Exist. Cases (7)	Urgent Pre-Exist. Cases (8)
Food Allergies, Voluntary Disclosure	1.177 (0.489)		0.886 (0.361)		0.653 (0.273)		1.364 (0.569)	
Voluntary Disclosure	0.911 (0.094)		1.084 (0.107)		1.240** (0.108)		0.860* (0.077)	
Food Allergies, Mandatory Disclosure		0.676 (0.199)		1.400 (0.408)		1.295 (0.366)		0.770 (0.212)
Mandatory Disclosure		1.311*** (0.100)		0.810*** (0.061)		0.87* (0.063)		1.216*** (0.08)
Food Allergies	4.23*** (1.54)	4.62*** (0.777)	0.25*** (0.09)	0.23*** (0.038)	0.29*** (0.105)	0.234*** (0.041)	3.57* (1.263)	4.25*** (0.722)
Number of Patients	9,233	13,983	9,368	14,179	9,370	13,983	9,505	14,179

This specification evaluates if the information campaigns affect the intensity of allergies. I zoom in on patients who visited hospital outpatient departments and who were diagnosed with food allergies, and analyze whether the health warnings change the share of acute cases compared to non-urgent cases. The share of urgent visits may rise if manufacturers choose not to label allergens causing more severe allergic reactions or products containing more of the risky ingredients, and if consumers erroneously consider products without warnings to be safer. The share of non-urgent OPD visits may increase if consumers need to discuss recently available health warnings, or if patients need to renew their prescription to manage their allergies. As for the urgent cases, I differentiate between less informed consumers, who have been living with their disease for less than three months, and compare them to more informed consumers. Since the latter category has been living with allergies for longer, they have more information about how to combat their disease, and thus they are likely to benefit the most from the information disclosure.

I analyze the effect of a product quality disclosure on the urgency of allergy visits using individual level data. The outcome variable measures the probability that a patient i visits an OPD h located in a state s at time period t with a certain urgency type, given she is diagnosed with allergies or control group diseases. Difference-in-differences framework compares patients diagnosed with food allergies to those diagnosed with control group diseases in the pre- and post-intervention periods. The definition of various urgency types of a visit is provided in Appendix A. This model estimates different logit fixed effects regressions for different intensity types. In contrast to multivariate logit, this setup allows the estimates to vary across different urgency categories.

Since both voluntary and mandatory allergen disclosure affects the entire country, I compare food allergies to a synthetic control group represented by a weighted average of non-allergy diagnoses, with weights chosen so that the resulting synthetic "food allergies" best reproduce the values of a set of predictors of food allergy visits prior to 2001, when the first allergen labeling regulation went into effect. The set of predictors includes patient socio-economic characteristics including their race, gender, and age; patient insurance characteristics; and hospital characteristics including their location and ownership status. Synthetic Control Group controls for unobserved advancements in medical technology targeting symptoms similar to food allergies.

Note 1: Synthetic Control=0.466*Bronchitis+0.31*Pneumonia+0.224*Skin Reactions.

Note 2: In all regressions, while not reported, I also include the following controls: (i) patients' socio-economic characteristics including their race, gender, and "established patient" status, (ii) patients insurance characteristics, (iii) Census records on education, income, and English literacy reported for an OPD county, (iv) state fixed effects, polynomial year time trend, months fixed effects (definitions of the variables are provided in Appendix A). Stars denote significance levels: 99 percent confidence level (***), 95 percent confidence level (**), and 90 percent confidence level (*). Data Source: NHAMCS outpatient department records and Census data for 1997-2010.

CHAPTER 2

PRODUCT LIABILITY AND REGULATION

WHEN CONSUMER LABEL-READING EFFORT COUNTS

by Maria Arbatskaya¹ and Maria Vyshnya Aslam²

Abstract

This paper examines the role of product liability and mandatory disclosure regulation in managing product risks (e.g. food allergens in packaged foods). In the model, the firm chooses a level of care that stochastically determines how risky the product is. If the risk level exceeds the critical level for disclosure, the firm must place a warning label on the product. Consumers have to expend label-reading efforts in order to find, read, and understand warning messages on the labels. We find that from the consumer perspective, firm and consumer care levels are strategic substitutes. At the same time, when product liability is weak, firms view care levels as strategic complements. We then explore how changes in product liability and warning label visibility affect the equilibrium levels of care, expected harm, firm profits, and consumer payoffs.

¹Department of Economics, Emory University, Atlanta, GA 30322-2240. Email: marbats@emory.edu.

²Department of Economics, Emory University, Atlanta, GA 30322-2240. Email: mvyshny@emory.edu.

Introduction

Every day, consumers decide whether to buy products that may present health risks. People shop for yogurt and pastries that may contain carcinogens or life-threatening allergens, they drive cars manufactured with certain safety features, they do their laundry with detergents containing benzene, they combat a disease with medications that may have side effects, they assess the quality of their happy-hour drinks and breast implants, and they buy a house at a certain distance from air-polluting plants.

In some of these cases, consumers are not fully informed of the risks they face. There can be a number of reasons why consumers lack safety-related information. Some consumers do not purchase a product frequently. Others fail to detect changes in its characteristics. The public may be unaware of the possibility of harm, for example, in the case of odorless and invisible carcinogenic agents. Finally, complex products require a buyer to have an expert knowledge in the field, which may be too costly to obtain.

There is a general consensus that the asymmetric awareness of buyers and sellers of the safety level of a product needs to be corrected by either regulation or litigation efforts. The main debate is about how to design the best policy. An intervention policy has to be chosen with caution. Although disclosure mandates can ensure that manufacturers provide information to consumers about safety features of the product (for example, by using a warning label), the mandates do not guarantee that consumers read and understand warning labels. It is important then to set visibility and clarity standards for the warnings in such a way that consumers have incentives to read them. In a similar vein, a strong liability system that compensates consumers for damages does not provide buyers with incentives to exert effort and inspect warnings.³ The main goal of this paper is to

³This is well-recognized in the literature on torts. See a survey by [Daughety and Reinganum \(2013\)](#).

analyze the interactive effects of regulation and litigation on firm and consumer care efforts, and the expected harm associated with products that have risk attributes.

Food allergen labeling regulation provides a fitting example of an intervention policy. It is important for consumers to be informed about allergy-related health risks, because food allergies are a growing problem of the society, and the main way to combat the disease is to avoid the food containing allergens.⁴ Therefore, food allergen labels can serve an important role in reducing the cost of allergy-related healthcare costs. The federal mandate for disclosing allergen information in packaged foods is embedded in the Federal "Food Allergen Labeling and Consumer Protection Act" (FALCPA) introduced by the FDA in 2004. This document mandates labeling eight major allergens for packaged food. It also sets uniform criteria for positioning the warning on food labels and specifies standards for warning label transparency. In this paper, we examine how the design of the disclosure mandate and liability system affect both consumer ability to find and understand warning labels and also firm investments in reducing product risks.

To achieve these goals, we develop a model in which a firm chooses a level of care that stochastically determines allergen content in food, given a legal and regulatory environment. The main novelty of our approach is in recognizing that consumers have to expend label-reading effort in order to find, read, and understand warning messages. Importantly, the consumer reading effort is endogenous. It depends on the strength of product liability, warning label visibility, precision of the disclosure standard, consumer susceptibility to the risk, the cost and ease of reading the warning, consumer expectation about the product risk, and the level of consumer harm. We find that from the consumer perspective, firm and consumer care levels are strategic substitutes, while for the firm they are strategic complements, provided that the liability rule is sufficiently weak.

These findings have important implications for the choice of policies aimed at reducing the

⁴The number of food allergies in the US has been on a rise, but so far no medication has been developed that can reliably prevent an allergic reaction to food (CDC, 2012; FDA, 2009).

expected harm from a product. Higher visibility of a warning and higher consumer risk perception tend to increase the equilibrium consumer and firm care and, thus, decrease the expected harm. By contrast, a stronger liability system shifts the burden of care from consumers to the firm, which tends to increase firm care and reduce consumer care, with an ambiguous effect on the expected harm. We also argue for setting more precise disclosure standards because they make warnings more informative, which encourages consumers to increase their label-reading effort.

The rest of the paper is organized as follows. In Section 2, we briefly review the food allergen labeling regulation in the U.S., which motivates our study. Section 3 provides a brief overview of the existing theory. The basic setup of our model is presented in Section 4. The consumer problem is analyzed in Section 5, and the optimal firm strategy is derived in Section 6. In Section 7, we look at the equilibrium levels of care in a simultaneous-move game between a firm and consumers and discuss alternative policy changes such as a stronger liability rule, higher visibility of the warning label, a more precise disclosure standard, and a higher perception of risk among consumers. Section 8 concludes. All the proofs are delegated to Appendix A.

A Motivating Example: Regulation of Allergen Labels

The national standards for labeling food allergens were set by the Federal “Food Allergen Labeling and Consumer Protection Act” (FALCPA), which was enacted in July 2004 and became effective in January 2006. The FDA introduced this law in response to a sharp decade-long increase in a number of allergies, especially among patients under the age of 15 (CDC, 2012; FDA, 2009). The mandate was also necessitated by insufficient advancement in treatment of the disease. As of today, there are limited cures for allergies, and the most successful method of managing the disease is to avoid the food containing allergens (Bischoff, 2007; Vierk et al., 2007; Boyce et al., 2010). It is thus crucial for consumers to have access to information about allergens in food.

The law targets the eight most common allergens responsible for 90 percent of all food allergies – milk, eggs, fish, Crustacean shellfish, tree nuts, peanut, wheat, and soybeans. These allergens trigger reactions of various intensity. Peanuts, tree nuts, fish and shellfish are reported to cause the most severe reactions observed in less than an hour after contact with the allergen. Other ingredients - milk, eggs, wheat, and soybeans - cause milder allergies that might be observed within a couple of hours ([Keet and Wood, 2007](#)). FALCPA does not take into account the intensity of allergic reactions and mandates labeling *any* amount of the allergens.

The mandate sets uniform standards for displaying the warning on food labels. First, FALCPA bans the use of Latin terminology and requires listing the major allergens “in plain and clear English.” Second, it bans fine prints. Finally, it outlines the standards for positioning the warning. The allergens may be mentioned in parentheses immediately after the ingredient (“casein (milk)”). Alternatively, the statement “contains (allergen source)” may immediately follow or be adjacent to the list of ingredients (e.g. “contains peanuts”). FALCPA regulation of the display of allergy information is aimed at making it easier for consumers to find and understand warning labels. Figure 2.1 shows an actual label that complies with FALCPA.

Allergy warnings are proven to be an essential factor in determining consumer food choices. Surveys of allergic consumers who attended medical facilities or participated in allergy trainings document that 85-95 percent of respondents read labels at the time of purchase or food preparation. More than 80 percent of consumers who have allergies contact manufacturers for more information if the label is ambiguous ([Simons et al., 2005](#); [Ahn et al., 2008](#)). These studies also link FALCPA allergy warnings to improvements in consumer awareness about product safety. For instance, 95 percent of respondents indicate that FALCPA regulation made it easier to find allergens on labels, and more than 70 percent feel more confident about label accuracy ([Ahn et al., 2008](#)).

Overall, how much attention consumers pay to allergen warnings depends on several fac-

Figure 2.1: A Label That Complies With the Federal Regulation



tors, including consumer susceptibility to the allergen, their awareness about the legislation, and the visibility of the messages. Adults are generally familiar with the symptoms and sources of their allergies, since most allergies develop under the age of 15. However, they may not realize that changes in food processing that occur over time affect their susceptibility to allergens. For instance, when manufacturers switch from using fried and boiled peanuts to peanut roasting and emulsification, this intensifies peanut allergies. Similarly, an increased use of antacids and antibiotics in food results in an exposure to more intact protein, which leads to more intense reactions to the same allergens (Cochrane et al., 2009). Consumer sensitivity to food allergens is also affected by “cross-reacting” allergens. Since all allergies are triggered by the same genes, patients with food allergies often react to a variety of non-food allergens. For instance, seafood, peanuts, tree nuts, and soy cross-react with mite, birch, lupin, and ragweed pollen (Heratizadeh et al., 2011; Boyce et al., 2010). Therefore, food allergies may intensify during pollination season.

Consumers' ability to react to allergy warnings is also determined by the visibility of the message. Overall, 95-99 percent of allergic consumers are able to recognize the message if allergens are located in a separate list, and only 60 percent notice labels where allergens are reported in parentheses right after the ingredient (Simons et al., 2005; Lemon-Mule et al., 2007; Ahn et al., 2008).

Some consumers have inadequate knowledge about labeling, since they are not aware of legislative nuances (Fortin, 2006). Only about 30 percent of surveyed allergic patients know that FALCPA exempt from labeling raw meat, poultry, and egg products, since they are regulated by the USDA's Food Safety and Inspection Service. A large proportion of allergic patients do not know that the legislation does not apply to unpacked food placed in wrappers, carry-out boxes, or other containers after being ordered by a consumer. Finally, some consumers might be unaware that the FDA did not require manufacturers to relabel products manufactured prior to January 2006 (Vierk et al., 2007; Ahn et al., 2008).

In contrast to regulation, which has significantly affected consumer and firm behavior regarding food safety, the impact of the litigation is less clear. Despite the prevalence of food allergies, there is little history of food allergen litigation in the U.S. Roses (2011) reports no litigation cases prior to 1992, only six cases between 1992 and 2000, and no cases in the later period. The lack of food allergen litigation can be explained by the general difficulties of proving the case and by out-of-court settlements. Cases related to severe allergic reactions are hard to prove, while mild reactions might not be compensatable at all. For instance, in 2007 *Moore v. P.F. Chang's China Bistro, Inc.*, the plaintiff had difficulties in proving that her hospitalization resulted from her exposure to shellfish at the defendant's restaurant rather than from her blood pressure medications. With milder allergies, courts often dismisses food allergy claims since the alleged harm is temporary and mild – they cause discomfort rather than disability (Roses, 2011). Another reason for a limited food

allergen litigation history is the pre-court case settlement. Details of settlements are generally kept confidential, so it is difficult to assess their frequency. However, the details of the most prominent cases shed some light on this issue. For instance, in 1994, a 33-year old woman, who was allergic to nuts, died after she digested a sandwich that contained pine nuts. She had been notified that the sandwich was free of nuts. The decedent's estate filed a lawsuit seeking 10.4 million in damages, and the case never went to trial (Roses, 2011). Settlements are also a likely explanation for the lack of procedural history. Regardless of the reasons, the limited number of food allergy litigation cases implies that product liability related to food allergies is weak in the sense that plaintiffs are not likely to recover damages.

Food allergen labeling regulation is an interesting and important example of mandated disclosure of product risks to consumers. In this context, we can examine how a firm chooses the safety level for its product depending on the liability system and on the mandated precision and visibility of warning messages. We can also study how consumer effort on inspecting and understanding the warning labels depends on visibility and disclosure standard precision. Importantly, in the case of food allergies, both consumer and firm efforts are endogenous and interdependent. Our theory aims at capturing this interdependence.

Theory Review

The use of regulation and liability tools to correct information asymmetries in the market is widely discussed in economic literature. Early papers question the need for regulation as such and examine sellers' incentives to disclose product quality voluntarily. According to the "unraveling result," sellers will always disclose their quality if consumers are homogeneous and rational, the good is of experience type, disclosure is costless, and the distribution of available quality is public information (Grossman, 1981; Milgrom, 1981; Fishman and Hagerty, 1990). If these assumptions

hold, the best-quality firms would pioneer at disclosing their quality, followed by a cascade of firms offering the next-best quality until all but the worst firms disclose.

Later papers relax some of the assumptions behind the “unraveling result” and outline a set of conditions preventing manufacturers from disclosing their quality. If product quality is privately observed by firms and disclosure is costly, or if producers can coordinate on disclosure decisions (as in a cartel), each firm chooses to disclose only if its quality is above a certain threshold (Jovanovic, 1982; Board, 2009; Levin, Peck and Ye, 2009). The lack of full disclosure can then provide a rationale for the use of disclosure mandates.

Another strand of literature shifts the emphasis from manufacturers’ willingness to reveal the quality of their product towards consumers’ ability to comprehend such messages. These studies point out that a larger number of producers and messages as well as an increasing sophistication of the messages make it harder for consumers to become fully informed (Anderson and Renault, 2006; Guo and Zhao, 2009; Harbaugh, Maxwell and Roussillon, 2011; Harbaugh and Rasmusen, 2013). Similarly, if it is costly for consumers to process product quality information, this may discourage consumers from buying a product even if the deal is beneficial to both parties (Rasmusen, 2001).

Finally, several papers synthesize the consumer-driven and firm-driven approaches by studying the manufacturers’ willingness to disclose quality conditional on consumers’ prior beliefs about product quality. For example, Fishman and Hagerty (1990) and Kamenica and Gentzkow (2011) demonstrate that manufacturers may prefer limited disclosure. Disclosure mandates may then be warranted. However, a mandate will adequately compensate for market imperfections only if a regulator has complete information about the harm to consumers, injurers’ benefits from taking actions and the cost of precaution. If regulators’ information is imperfect, consumers who actually suffer from the harm may have better information about the source and the extent of the harm. Therefore, victims may be considered more appropriate enforcement agents, suggesting the desirability of a

liability tool (Shavell, 2007; Viscusi, 2007).

The role of a liability system in affecting product safety is discussed in numerous studies. In general, strict liability increases firm care because it increases firm's liability costs and thus provides incentives for improving product quality (Polinsky and Rogerson, 1983; Viscusi and Moore, 1993; Daughety and Reinganum, 2013). Strict liability can be socially optimal in "unilateral accidents"⁵ if a firm is able to fully cover the harm it might cause. In our paper, we analyze a case of "bilateral accidents" - the situation when both the firm and consumer care decisions have an impact on the probability of harm. In particular, we study consumer care in the form of label-reading effort. We analyze how the consumer choice of care depends on firm care and vice versa. By examining the interactive effects of regulation and litigation on the equilibrium levels of care, we bridge the gap between the two streams of literature on mandatory disclosure and liability.

Model Setup

A firm manufactures a product that may contain an allergen. The allergen content in the product is denoted by $a \geq 0$. High levels of a indicate a high level of the allergen. Such foods are relatively unsafe for people to consume. Very low levels of a may correspond to a product that contains only traces of an allergen. Allergen-free products ($a = 0$) may describe foods produced using a separate production line or in a separate facility, which eliminates any contact with the allergen. We assume that the product is *safe* for consumers if the amount of an allergen does not exceed $a_0 > 0$. On the other hand, if $a > a_0$, then the product is potentially *unsafe* or risky. Parameter a_0 is the consumer tolerance level to an allergen.⁶

⁵Unilateral accidents are situations where one party (e.g. the firm) is solely responsible for accidents. Shavell (2007) provides a comprehensive classification of accident liability cases.

⁶The consumer tolerance level a_0 depends on the type of allergen. For some allergens (e.g. peanuts, tree nuts, or shellfish), the threshold dose of reactivity can be very small. For other allergens (e.g. milk, eggs, wheat) it is much larger (Keet and Wood, 2007). For simplicity, we do not consider individual consumer heterogeneity in the tolerance level, which could also be affected by some treatments.

The firm decides on the level of care, $y \geq 0$, that stochastically determines the allergen content a . Let $G(a; y)$ be the cumulative distribution function for the allergen content a in the product for a given level of firm care y . We assume it is increasing in a and y : $\partial G(a; y)/\partial a \geq 0$ and $\partial G(a; y)/\partial y \geq 0$. The probability that the product is unsafe is then $\Pr(\text{unsafe}) = P(y, a_0) = \Pr(a > a_0; y) = 1 - G(a_0; y) \in (0, 1)$. It is decreasing in y and a_0 : $\partial P(y, a_0)/\partial y \leq 0$ and $\partial P(y, a_0)/\partial a_0 \leq 0$.

It is assumed that the marginal cost of production $m(y)$ weakly increases in care $m'(y) \geq 0$. For example, the cost of adding real fruit to foods is high compared to adding artificial colors and flavors imitating fruit. At the same time, artificial additives are often produced using substantial amounts of allergens. We assume that the cost is convex in the firm's care: $m''(y) \geq 0$. That is, we assume that it becomes more costly to reduce the allergen content at higher levels of care. For example, it may require that foods containing allergens and allergen-free foods are produced on different technological lines or even in different facilities.⁷

The firm and consumers are risk neutral. Each consumer wants to buy at most one unit of the product. Consumers have a value v for the product that does not result in an allergic reaction. Let τ be the consumer's likelihood of developing an allergic reaction to the product that is potentially unsafe.⁸ If a consumer eats an unsafe food, she experiences an allergic reaction with probability τ and incurs a harm of $h > 0$.

The firm may have to compensate consumers for the harm associated with the consumption of the product. Let C be the uncompensated cost to the consumer of an allergic reaction. The

⁷There are many ways to manage risks associated with the unintentional presence of allergens in packaged foods. These include compiling a master list of all ingredients and raw materials used (including food additives, flavors and colorings), obtaining documentation from the suppliers of ingredients, managing production scheduling, shipping, handling and storage, following cleaning procedures, testing for allergens, employee training, and program evaluation. Labeling is critical for foods containing allergens.

⁸Consumers can be heterogeneous in their susceptibility to food allergies: some of them are not affected by the allergen, others have rare mild negative reactions (e.g. allergic rash or allergic sneezing), while some consumers are likely to have severe or life-threatening reactions (e.g. allergic anaphylactic shock). For simplicity, we assume here that all consumers have the same τ and discuss the implications of consumer heterogeneity in Conclusion.

uncompensated cost increases in the severity of harm h and decreases in the likelihood of damage recovery l ($l \in [0, 1)$ depends on the liability system and the decisions of the courts). In what follows we assume that $C = (1 - l)h > 0$, but we could also account for litigation costs. Parameter l can be interpreted as the strength of the liability system. High (low) levels of l correspond to strong (weak) liability, while $l = 0$ in the case with no liability.

Consumers do not know if a product is unsafe. They inspect product labels in search of a warning message and then make a decision on whether to buy the product. Consumers may have misperceptions about product safety. They believe that the probability that the product is unsafe is $P^e(y, a_0) = \lambda P(y, a_0) \in (0, 1)$, where $\lambda \geq 0$ measures the risk perceptions of consumers: $\lambda = 1$ corresponds to the correct prior assessment of risk; $\lambda < 1$ corresponds to underestimation of risk, and $\lambda > 1$ to overestimation of risk.⁹ By examining the product, consumers can update their prior to better assess the risk they face when consuming the product.

It is costly to read labels. We assume that there is a constant marginal cost to label-reading effort, $c > 0$. In choosing the optimal effort, consumers trade off the extra benefit of spending more time on looking for and examining the label and the cost of doing it. The benefit comes from a decrease in the likelihood that the consumer inadvertently consumes an unsafe product.

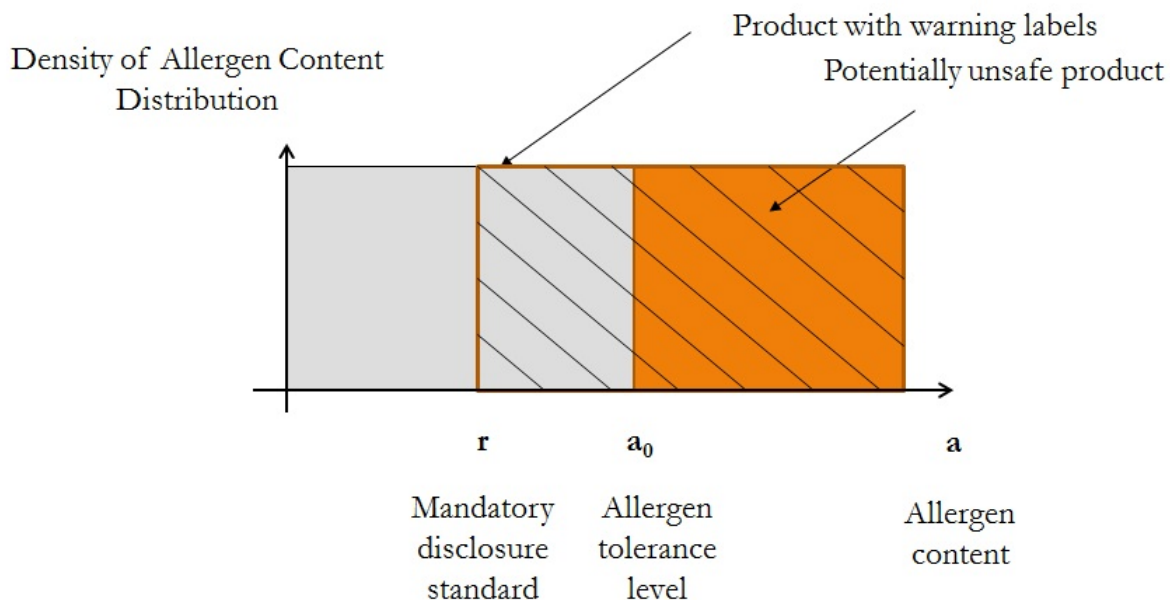
Under mandatory disclosure, the firm is required to include a warning message on the product's label if the product's allergen content a exceeds a critical level r . We assume that firms comply with the regulation and provide a warning label if and only if $a > r$. We also assume that the mandated threshold level for disclosure is lower than the allergen tolerance level a_0 : $r \leq a_0$.¹⁰ We say

⁹Consumers may overestimate or underestimate the risk of food allergies for several reasons. First, food allergies have the same symptoms as a wide range of non-food allergies (e.g. non-food allergic asthma, bronchitis, urticaria, dermatitis, etc.) Without a lab test, manifestations of non-food allergies can be easily attributed to food allergies and vice versa. Second, changes that occur in food processing over time may trigger more intense reactions in patients with a history of food allergies. For instance, switching from the use of fried and boiled peanuts to peanut roasting and emulsification intensifies peanut allergies. If consumers are unaware of manufacturer processes, they may underestimate the product risk.

¹⁰We could consider the case of a less strict disclosure standard ($r > a_0$), but this case seems to be of lesser practical importance because FALCPA requires firms to disclose any detectable levels of allergen.

that the disclosure standard is *exact* if $r = a_0$. In Section 7.4 we look at the effects of a more precise disclosure standard (r closer to a_0). In Figure 3 we show the levels of allergen content for which a product is potentially unsafe and warning labels are mandated, assuming a uniform distribution of allergen content.

Figure 2.2: Mandatory Disclosure Standard



Consumers know about mandatory disclosure and, therefore, believe that the probability that the warning label exists is $\Pr(a > r; y) = P^e(y, r) \in (0, 1)$.

The probability that a consumer finds and correctly understands the warning label depends on the label's visibility $b \geq 0$ and consumer reading effort $x \geq 0$. The transparency of the warning b reflects the prominence, clarity, or readability of the warning label (e.g. label font size, whether allergens are listed as a separate list or mentioned after each ingredient, and whether the message is in plain English). Higher levels of b indicate a more transparent label, i.e. a warning label that is easier for consumers to find and understand. We assume that, when present, the warning message will be discovered and understood by the inspecting consumer with probability $f(x, b) \in [0, 1]$,

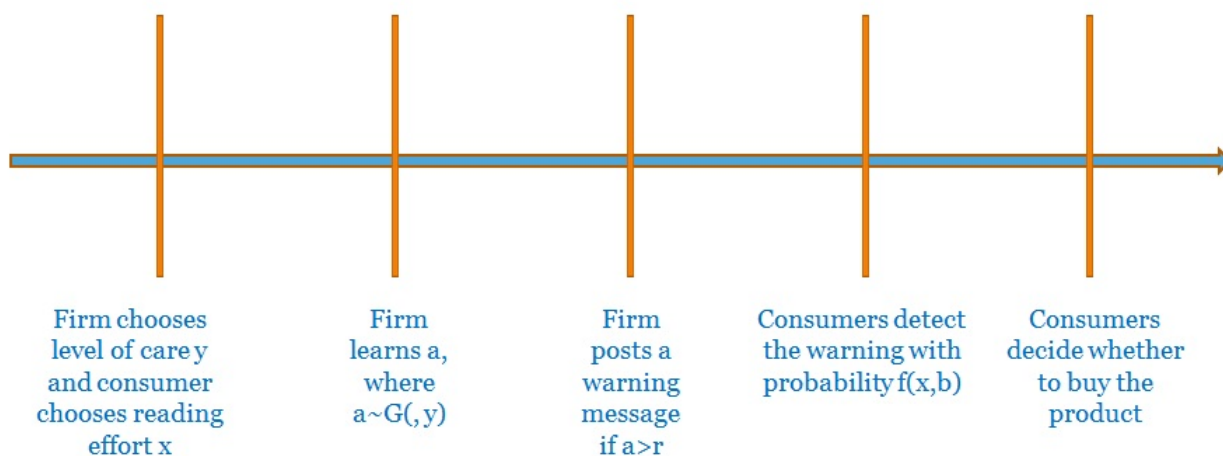
which satisfies the Inada conditions.¹¹ In particular, the discovery function is such that no effort implies no discovery for any positive visibility level $b > 0$, higher label-reading effort is more likely to result in a discovery of the warning label, provided it exists, and there are diminishing returns to effort. We also assume that the probability of discovery increases as the label becomes clearer: $\partial f(x, b) / \partial b > 0$ and that there is complementarity between transparency and reading effort, $\partial^2 f(x, b) / \partial x \partial b > 0$.

After spending effort x in examining the product's label, a consumer computes the likelihood that the product is safe, given the outcome of the inspection. The posterior probability is calculated using Bayes rule. Then, based on her assessment of risk, a consumer has to decide whether to buy the product. If consumers find the warning label, they do not buy the product if their sensitivity τ is sufficiently high. If consumers do not find the warning label, they always buy the product. If that were not the case the consumer would not have entered the market in the first place.

After we examine separately the consumer and firm problems in the next two sections, we will look for the Nash Equilibrium in a game where the firm and consumers make their care decisions simultaneously. The firm chooses the amount of care y . Consumers first decide whether to enter the market. Second, consumers decide how much time and effort, x , to allocate to reading the label. Finally, consumers choose whether to buy the product, given their assessment of the probability that the food is unsafe and their susceptibility to the allergen. In making the decisions, consumers know about the strength of the liability system l , mandatory disclosure standard r , the standard for transparency of the warning label b , and the price of the product p , but not the level of care y or allergen content a . Figure 2.3 shows the timing of decisions.

¹¹For any $b > 0$, as a function of x , the discovery function $f(x, b)$ is a continuously differentiable concave function strictly increasing in x ; it has the value of 0 at $x = 0$, and the limit of its first derivative is infinity as x approaches 0 and 0 as x approaches infinity.

Figure 2.3: Timeline For Decision-Making



Consumer Problem

To decide whether it is worthwhile to buy the product, a consumer has to assess the odds of it being safe. The consumer can examine the product label in search of a warning. If the warning label is present, the consumer discovers it with probability $f(x,b)$, where x is the consumer's reading effort and b is label transparency. If the product is sufficiently risky ($a > r$), the firm is mandated to disclose it by including a warning message on the product's label. When the product is sufficiently safe ($a \leq r$), no warning is issued by the seller, and the consumer cannot possibly discover it. We assume that $r \leq a_0$ because the current allergen regulation in the U.S. requires disclosure of any detectable levels of allergens (although not accidental traces of allergens).

After spending x amount of time and effort on label detection, a consumer who has not

detected a warning determines the posterior probability of the product being unsafe as follows:

$$\begin{aligned}
 P^{ND} &= P^{ND}(x, y) = Pr(\text{unsafe} | \text{No Detection}) \\
 &= \frac{Pr(\text{unsafe} \& \text{No Detection})}{Pr(\text{No Detection})} \\
 &= \frac{P^e(y, a_0)(1 - f(x, b))}{1 - P^e(y, r)f(x, b)},
 \end{aligned} \tag{2.1}$$

where $P^e(y, \cdot) = \lambda P(y, \cdot) = \lambda(1 - G(\cdot; y))$.

For the allergen warning to be detected, it must be present and the consumer must discover its presence by reading a warning label. Hence, the probability that an allergen is detected is equal to $Pr(\text{Detection}) = P^e(y, r)f(x, b)$. Then, the probability that the allergen is not detected equals $Pr(\text{No Detection}) = 1 - Pr(\text{Detection})$. When consumer fails to detect an allergen, it could be either because there is no warning label or because a consumer has failed to discover it. The probability that the warning label is not discovered and the product is unsafe is $Pr(\text{unsafe} \& \text{No Detection}) = P^e(y, a_0)(1 - f(x, b))$.

Clearly, greater effort on the part of consumers and more transparent labels allow consumers to reduce the probability of buying an unsafe product. The posterior probability of an unsafe product in the case of no detection decreases with x , b , a_0 , and r :

$$P^{ND} = P^{ND}(x, y; a_0, b, r, \lambda). \tag{2.2}$$

The risk of an allergic reaction goes down with consumer effort x , firm care y , visibility of warning label b , allergen tolerance level a_0 , and disclosure standard r .

For a consumer who has detected a warning, the posterior probability of the product being

unsafe is

$$\begin{aligned}
 P^D &= Pr(\text{unsafe}|\text{Detection}) \\
 &= \frac{Pr(\text{unsafe}\&\text{Detection})}{Pr(\text{Detection})} \\
 &= \frac{P^e(y, a_0)}{P^e(y, r)} \leq 1
 \end{aligned} \tag{2.3}$$

for $r \leq a_0$. When the disclosure standard is *exact* ($r = a_0$) then the discovery of the warning label means the product is unsafe for sure, $P^D = 1$. When the disclosure standard is not as precise, then $P^D < 1$ because detection does not imply that the product is unsafe in this case.

A consumer decides whether to buy the product given her susceptibility τ and her posterior assessment that the product is unsafe, which depends on the effort x the consumer spent examining the product and the outcome of the inspection. If the consumer buys the product, then the expected consumer payoff is $u(x) = v - p - cx - P^D(y)\tau C$ if the warning label is detected and $u(x) = v - p - cx - P^{ND}(x, y)\tau C$ otherwise. The consumer obtains $-cx$ if she does not buy the product.

Prior to the outcome of the investigation, the consumer decides how much effort to spend on looking for and reading the label. In deciding on the optimal level of effort, a consumer trades off the marginal benefit and marginal cost of reading the label. The marginal benefit comes in the form of a reduced probability of buying an unsafe product. The ex ante expected utility of a consumer who spends effort x in examining a product before knowing the outcome of the inspection and making the optimal purchase decision based on it is

$$\begin{aligned}
 EU(x) &= -cx + Pr(\text{no Detection}) \max \{v - p - P^{ND}\tau C, 0\} \\
 &\quad + Pr(\text{Detection}) \max \{v - p - P^D\tau C, 0\}.
 \end{aligned} \tag{2.4}$$

A consumer maximizes her expected utility by choosing a reading effort x^* . Let $\tau_D = \frac{1}{P^D} \frac{v-p}{C} = \frac{P^e(y, r)}{P^e(y, a_0)} \frac{v-p}{C}$. A consumer with $\tau \leq \tau_D$ buys the product regardless of the outcome of the in-

spection because the expected consumer utility is monotonically decreasing in x for such consumer. Hence, the optimal effort is $x^* = 0$ for $\tau \leq \tau_D$. Intuitively, if the decision to buy the product does not depend on the outcome of the inspection, there is no benefit to spending label-reading effort. The consumer remains rationally ignorant if $\tau \leq \tau_D$. The case of $\tau > \tau_D$ is more interesting, and we will assume that this is the case. By the definition of τ_D , a consumer with susceptibility $\tau > \tau_D$ will not buy a product if the warning label is detected. If no detection occurs, the consumer buys because otherwise the consumer would choose not to enter the market in the first place. Then, the expected consumer utility is $EU(x) = \Pr^e(\text{buy})(v - p) - cx - \Pr^e(\text{harm})C$, where $\Pr^e(\text{buy}) = \Pr^e(\text{No Detection}) = 1 - P^e(y, r)f(x, b)$ and $\Pr^e(\text{harm}) = P^e(y, a_0)(1 - f(x, b))\tau$. The consumer benefit from buying the product is $v - p$. The costs include the costs of reading the label and the costs of having an allergic reaction.

We can regroup the terms to find that

$$EU(x) = u_0 - cx + Bf(x, b), \quad (2.5)$$

where $u_0 = v - p - P^e(y, a_0)\tau C$ is the expected utility of buying the product without inspection and $B \equiv P^e(y, a_0)\tau C - P^e(y, r)(v - p)$ is the net benefit to the consumer from the discovery of the warning. The detection of the warning label allows the consumer to reduce the likelihood of harm, but it also means that the consumer would not buy the product and therefore would lose the surplus $v - p$. To have an interior solution, we assume that the benefit of discovery B is positive.

Assuming there is an interior solution for the optimal label-reading effort $x^* > 0$, it is implicitly defined by the first-order condition:

$$B \frac{\partial f(x^*, b)}{\partial x} = c. \quad (2.6)$$

The relationship between consumer and firm care depends on how the benefit of reading is influ-

enced by the care of the firm. Since $\frac{\partial^2 EU}{\partial x \partial y} = \frac{\partial B}{\partial y} \frac{\partial f}{\partial x}$, we find that $\text{sign}\left(\frac{\partial^2 EU}{\partial x \partial y}\right) = \text{sign}\left(\frac{\partial B}{\partial y}\right)$. For a consumer with susceptibility $\tau > \hat{\tau} \equiv \frac{v-p}{C} \frac{\frac{\partial P^e(y,r)}{\partial y}}{\frac{\partial P^e(y,a_0)}{\partial y}}$, $\frac{\partial B}{\partial y} < 0$ and $\frac{\partial^2 EU}{\partial x \partial y} < 0$. Therefore, from the consumer perspective, care levels by firm and consumer are strategic substitutes for consumers with sufficiently high susceptibility.¹²

Proposition 1. Equilibrium Consumer Effort. *There exists a unique interior equilibrium consumer label-reading effort $x^* > 0$. It is positively related to the warning label visibility standard b , disclosure standard r , price of the product p , consumer susceptibility τ , cost of getting sick C , and consumer expectations about allergen content λ , and it is negatively related to valuation of the product v , tolerance level a_0 , and cost of inspection c . Consumer reading effort is negatively related to the firm's level of care y if $\tau > \hat{\tau}$.*

Using notation, we find that

$$x^* = R_x \left(\underset{-}{y}, \underset{+}{b}, \underset{+}{r}, \underset{-}{v}, \underset{+}{p}, \underset{-}{a_0}, \underset{+}{\tau}, \underset{+}{C}, \underset{-}{c}, \underset{+}{\lambda} \right). \quad (2.7)$$

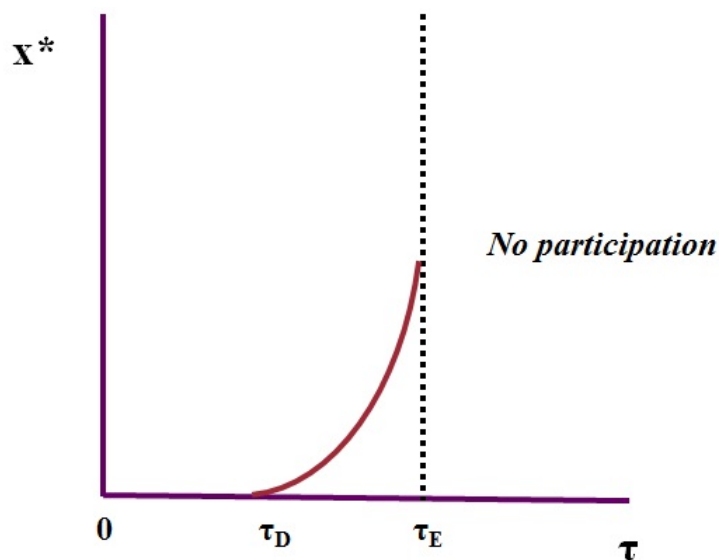
The results are intuitive. A consumer would extend label-reading effort as long as the marginal benefit exceeds the marginal cost, c . The marginal benefit comes from an increase in the probability of finding the warning label times the benefit of the discovery, B . It is high when the consumer is likely to develop a severe allergic reaction (a_0 is low and τ and C are high), consumer perceives the product to be risky (λ is high), the net value of the product $v - p$ is low, and the disclosure standard is more precise (r is closer to a_0). Hence, the consumer would spend less reading effort under these conditions. Intuitively, label visibility encourages consumers to spend more label-reading effort, and at least high-susceptibility consumers reduce their care level when the firm produces a safer product.

¹²When regulation is exact or distribution of allergen is uniform, then all consumers who read labels ($\tau > \tau_D$) are of that type because $\hat{\tau} = \tau_D = \frac{v-p}{C} \frac{P^e(y,r)}{P^e(y,a_0)}$. If $\tau_D > \hat{\tau}$, then it is possible to find $\tau \in (\tau_D, \hat{\tau})$ for which $\frac{\partial B}{\partial y} > 0$ and $\frac{\partial^2 EU}{\partial x \partial y} > 0$. For such a consumer, care levels by firm and consumer are strategic complements.

Corollary 1. *If $C = (1 - l)h$, then the equilibrium consumer effort spent on label inspection is positively related to harm and negatively related to liability l .*

Figure 2.4 shows how the equilibrium consumer effort varies with consumer susceptibility τ .

Figure 2.4: Equilibrium Effort by Consumer as a Function of Susceptibility



A consumer with $\tau < \tau_D$ would buy regardless of whether she finds the warning or not. Therefore, she does not find it rewarding to read labels. A consumer with $\tau > \tau_D$ would buy only if she does not discover a warning. It is optimal for her to spend some effort reading labels, and the optimal effort she chooses increases in her susceptibility to the allergen τ . Let τ_E be the type of consumer who is indifferent between participating and not participating in the market, $EU(x^*(\tau_E); \tau_E) = 0$. Consumers with $\tau > \tau_E$ would choose to avoid the product group altogether. They would choose not to participate in the market because it is costly to search for warnings and it is unlikely that the product will bring a positive net benefit given the risk they face.

In what follows, we focus on the case of a homogeneous group of consumers with susceptibility $\tau \in (\tau_D, \tau_E)$ and normalize the number of consumers to one.¹³ Suppose a consumer spends

¹³The case of heterogeneous consumers can be similarly analyzed. See the discussion in the Conclusion.

effort x on reading the label. Then, the probability that the consumer buys the product (the demand) is

$$D(x, y) = 1 - P(y, r)f(x, b) \quad (2.8)$$

because the consumer buys the product if and only if the warning is not discovered. Lemma 1 follows.

Lemma 1. Properties of Demand. *The demand for the product is negatively related to consumer care x and positively related to firm care y . For given levels of care, demand is increasing in the disclosure standard r and decreasing in the transparency of the warning label b :*

$$D = D \left(\begin{array}{c} x, y, b, r \\ - \quad + \quad - \quad + \end{array} \right). \quad (2.9)$$

The probability of harm is the probability that the product is risky and the warning is not detected. A consumer who buys the product after exerting effort x faces the expected harm of

$$H = \Pr(\text{harm})h = P(y, a_0) (1 - f(x, b)) h\tau. \quad (2.10)$$

Lemma 2 follows.

Lemma 2. Properties of the expected harm H . *The expected harm is negatively related to consumer care x and firm care y . For given levels of care, the expected harm is decreasing in visibility of the warning label b , safety threshold a_0 , and it is increasing in consumer susceptibility to allergen τ and harm level h :*

$$H = H \left(\begin{array}{c} x, y; b, a_0, \tau, h \\ - \quad - \quad - \quad - \quad + \quad + \end{array} \right). \quad (2.11)$$

Lemma 2 shows that the expected harm is directly affected by label transparency b , safety threshold a_0 , consumer susceptibility to allergen τ , and harm level h . It also depends indirectly on a number of parameters through the endogenous care decisions made by the firm and consumers.

Seller's Problem

A firm maximizes its profits by choosing the amount of care y to spend designing and manufacturing the product. Assume that the prominence of the warning message b is regulated in the market. Firm's costs consist of two components: production costs and liability costs. We assume that the liability costs are proportional to the expected consumer harm. Denote by $L = lH$ liability costs, where l measures the strength of the liability system. We will assume that product liability is weak in allergy cases. This is in part because it is usually hard to prove that an allergic reaction was caused by the consumption of a specific product.

We start by looking at how a monopoly chooses the amount of care y , given consumer effort x , price p , and clarity of the label b .¹⁴ Firm's profits are

$$\pi = (p - m(y)) \times D(x, y) - lH(x, y) \quad (2.12)$$

The choice of care affects the production and liability costs. Higher levels of firm care are associated with higher marginal costs of production and lower liability costs. The demand is increasing in firm's care.

The demand depends on firm care because firm care affects the distribution of allergen in the product. Firm care makes the product safer and reduces the probability of disclosure. Since disclosure is mandated and firms know the actual allergen content, the likelihood of disclosure depends on the true distribution of allergen content. It follows that under mandatory disclosure, the firm is not just minimizing the total costs but also has to account for the effect of its care on the demand. This is in contrast with asymmetric information models of firm care, in which consumer

¹⁴In the analysis of firm's decision-making, we choose to focus on the care decision. The firm could also set the product's price p and vary the visibility of the warning label b . We could also examine a game in which the seller is the leader. In such a game, the firm makes its care level known to consumers prior to the consumer's effort decision. This scenario may be less plausible than the current setup because it may be hard for a firm to credibly commit to a level of care. Still, we will be able to make predictions about how this version of the game will be played.

demand typically does not depend on the care chosen by the firm because consumers make decisions based on their beliefs about the safety of the product, not on the actual safety (see an excellent discussion in [Daughety and Reinganum \(2013\)](#)).

Let us examine how monopoly's choice of care y affects its profits:

$$\frac{\partial \pi}{\partial y} = -m'(y) \times D(x, y) + (p - m(y)) \times \frac{\partial D(x, y)}{\partial y} - l \frac{\partial H(x, y)}{\partial y}. \quad (2.13)$$

The first term is the extra cost of care. It is proportional to the demand. The second term is the benefit due to higher demand that is realized because of a lower likelihood of disclosure. The last term is the benefit from lower liability costs due to higher firm care. Proposition 2 demonstrates how the parameters of interest affect the firm's choice of care.

Proposition 2. *Under a sufficiently weak liability system, firm care is a strategic complement to consumer reading effort. The optimal level of care y^* is increasing with liability l , warning label transparency b , price p , harm h , and susceptibility to allergen τ :*

$$y^* = R_y \left(\begin{matrix} x, & l, & b, & p, & h, & \tau \\ + & + & + & + & + & + \end{matrix} \right). \quad (2.14)$$

The firm prefers that consumers read warning labels less.

Note that firm care does not directly depend on consumer valuation of the product v , consumer risk perception λ , and the cost of inspecting the warning label c . These parameters directly influence only consumer decisions.

Whether the efforts of the firm and consumers are complementary from the firm's perspective depends on the sign of $\frac{\partial^2 \pi}{\partial x \partial y}$. In the proof of Proposition 2 we show that $\frac{\partial^2 \pi}{\partial x \partial y} > 0$ holds for sufficiently low l . Therefore, for a sufficiently weak liability system a firm considers its and consumer efforts as complementary.

Equilibrium

To find the equilibrium in the model where consumers and firms simultaneously make their care decisions, we have to combine our findings from the previous two sections. We will assume that the liability rule is sufficiently weak. From the consumer perspective, reading effort and the firm's choice of care are strategic substitutes. For the firm, they are strategic complements. Therefore, consumer best-response is downward-sloping while firm best-response is upward-sloping. The intersection of the best response functions is the equilibrium pair of care decisions (x_E^*, y_E^*) . We will next examine how alternative policy tools affect the equilibrium levels of care, the expected harm, firm profits and consumer payoffs.

Changes in the Strength of the Liability System

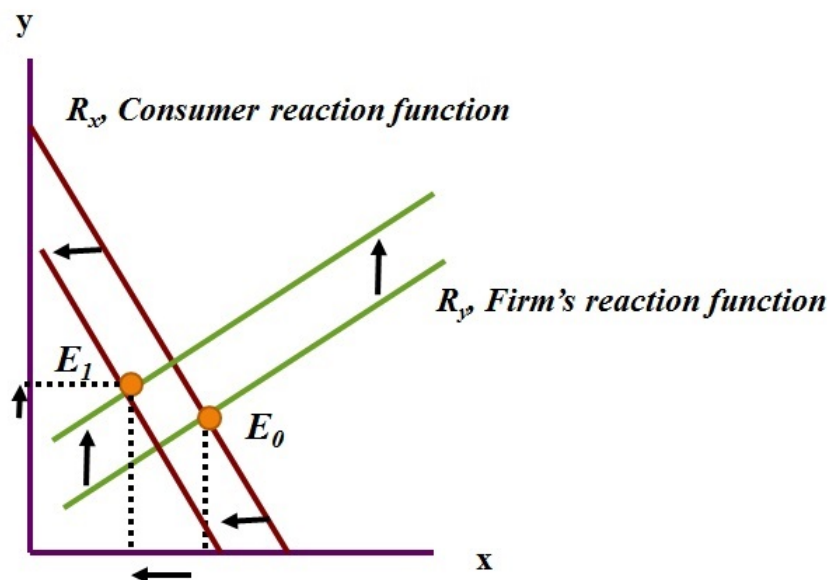
In this subsection, we discuss the effects of changes in the liability strength l . A marginally stronger liability l reduces consumer reading effort for any level of firm care. At the same time, it increases firm care, keeping consumer reading effort constant. The overall effect is a reduction in consumer care and an increase or decrease in firm care.

Proposition 3. *A marginal increase in the strength of product liability l results in lower equilibrium consumer care. Firm care tends to increase in l , especially for a low visibility standard.*

Figure 2.5 shows what happens to the equilibrium as product liability becomes stronger: the equilibrium moves from E_0 to E_1 , with higher firm care and lower consumer reading effort.

A stronger liability results in an ambiguous change in the expected harm. It reduces the expected harm by stimulating the manufacturer to respond with a higher level of care. However, it guarantees consumers a higher compensation and thus discourages them from carefully reading warning labels. This increases the expected harm.

Figure 2.5: Stronger Liability



The strength of liability affects firm's profits as follows. A stronger product liability has a negative direct effect on firm's profits. But there is a positive indirect effect due to a reduction in consumer reading effort. If the direct effect dominates, then the firm favors lower levels of liability (in other words, firm may prefer a higher burden of proof in product liability cases). Changes in liability have ambiguous effects on the equilibrium expected utility as well.

If consumer reading effort is determined exogenously, the firm prefers a lower liability standard, while consumers prefer a higher liability standard. The overall impact of stricter liability rule on the expected harm would be negative. We show that the endogeneity of consumer effort can change these predictions. Thus, a policy that only allows for supply-side responses may fail to achieve a desired outcome (such as a reduction in the expected harm) when demand-side responses are present. One has to think about the unintended consequences of changes in regulation and liability system – their effects on consumer care.

Changes in Visibility of Warning Labels

In this subsection, we discuss the effects of changes in the visibility standard for warning messages. From the firm's perspective, higher visibility increases the probability that the consumer discovers an existing warning label. For a given level of product safety, this implies a higher loss in demand and lower liability costs for the firm. Therefore, when the government mandates higher visibility, a firm responds by increasing its level of care. From the consumer perspective, the overall impact of higher transparency on consumer care is less clear. On the one hand, higher visibility directly induces consumers to spend more time and effort on examining the warning label. On the other hand, an increase in firm care that results from higher visibility indirectly discourages consumers from expanding label-reading effort.

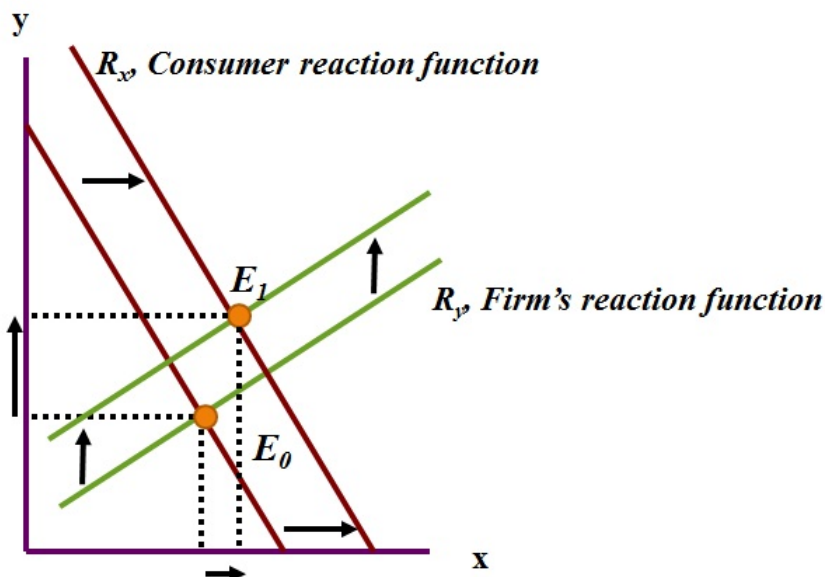
If the liability rule is sufficiently weak, the direct effect on the reading effort dominates the indirect effect through firm care, and the overall effect of higher visibility on consumer care is positive. Proposition 4 summarizes the effects of changes in warning label transparency.

Proposition 4. *A marginally higher visibility b of warning labels increases the equilibrium care by the firm. A higher visibility tends to increase consumer care, especially when starting with low levels of visibility, which guarantees that the expected harm tends to be lower when warning labels are more visible. Consumers always favor more visible warning labels, while the firm tends to prefer less visibility.*

Figure 2.6 illustrates how the equilibrium changes as the visibility of warning messages b increases.

Proposition 4 implies that under a sufficiently weak liability standard, one of the ways to reduce the expected harm to consumers is to mandate a higher transparency of the health risk warnings. This will induce both the firm and consumers to choose higher levels of care. We find

Figure 2.6: Higher Visibility of Warning Messages



that more transparent labels unambiguously decrease the expected harm from allergic reactions to the product. First, higher visibility makes it more likely that consumers discover the warning label, which directly reduces the expected harm. Additionally, it induces consumers to inspect the warning labels more attentively and stimulates the firm to choose a higher level of care, both of which further decrease the expected harm.

In equilibrium, consumers favor more visible warnings because they are easier to find and read, and because higher visibility prompts the firm to offer a safer product. On the contrary, firm's profits tend to decrease in the visibility of warning labels. On the one hand, more visible warnings result in lost demand. On the other hand, a higher visibility decreases liability costs. Under a sufficiently weak liability standard, the first effect dominates, and the firm prefers warning labels to be less visible.

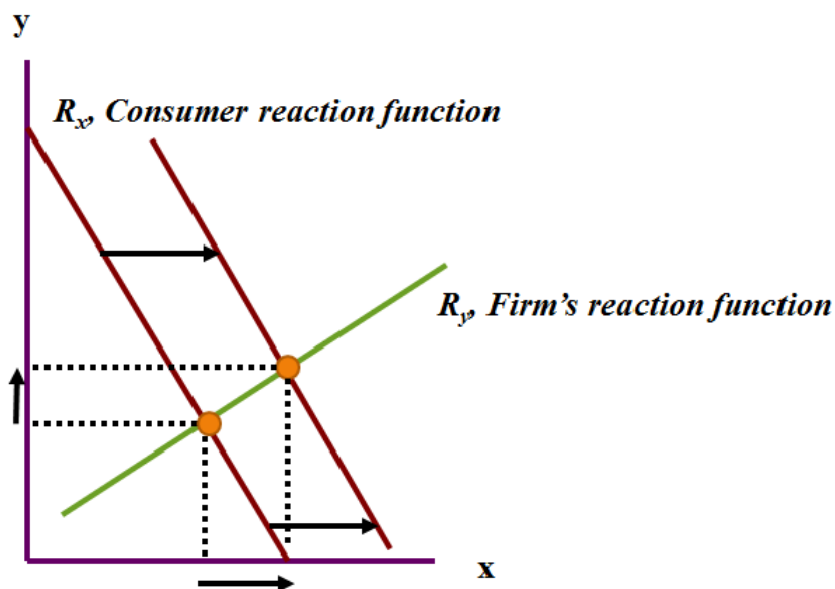
What our results then suggest is that, under weak liability, firms may not have incentives to make warning messages easy to find and comprehend. When firms have an ability to choose the way the label is displayed and how transparent it is, they may not opt to make the warnings visible. This

would explain why policymakers set the minimum transparency standard. For instance, FALCPA bans fine prints and mandates labeling allergens in English rather than in Latin.

Changes in Consumer Perceptions

Product risk perception parameter λ directly affects only consumer decisions. For instance, if consumers overestimate the risk ($\lambda > 1$), they spend more time and effort on inspecting warning labels than if they had more accurate expectations. Risk perception parameter λ does not directly influence firm decisions because firm's profits depend on the probability that the label is *posted*, which depends on the actual risk level. Liability costs also depend on the actual rather than perceived expected harm. Figure 2.7 shows the effects of a higher consumer risk perception λ .

Figure 2.7: Higher Risk Perception



Proposition 5. *A higher risk perception by consumers results in a higher equilibrium care by the firm and consumers. The expected harm is lower.*

Intuitively, if consumers believe that the product is more risky, they will read labels more

carefully. Under weak liability, this prompts the firm to increase its level of care as well. As a result, higher consumer risk perception in equilibrium results in higher levels of care by both the firm and consumers. The expected harm is sure to decrease.

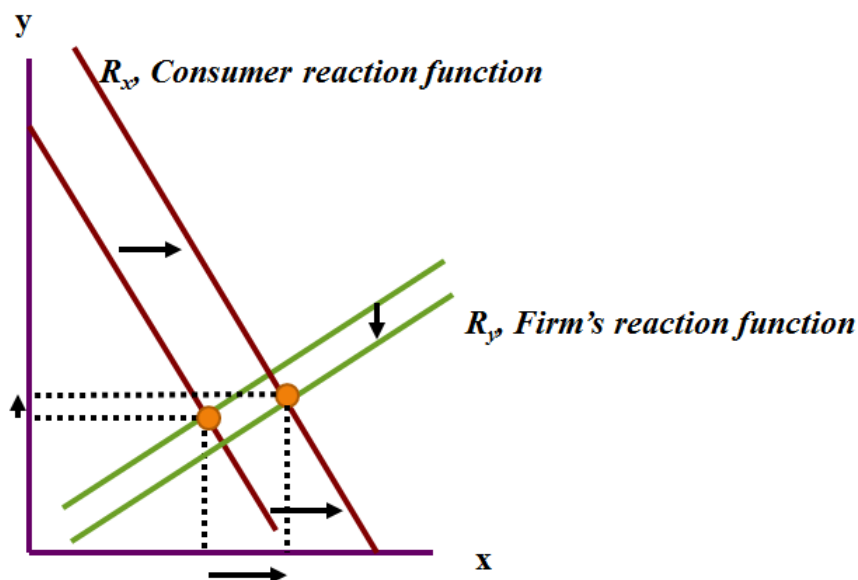
Changes in Disclosure Standard

We have shown that stronger liability and/or higher visibility of warning messages can reduce the expected harm. A change in the critical level for mandatory disclosure can also affect the equilibrium levels of care and the expected harm. Recall that firms have to display a warning label if the allergen level a exceeds the critical level r (called disclosure standard). We continue to assume that r is below the safety threshold a_0 ($r \leq a_0$).

Consumer demand is affected by the disclosure standard r , but the expected harm and liability costs depend on the safety threshold a_0 rather than on r . Importantly, the disclosure standard affects the informativeness of the warning label. If regulation is exact ($r = a_0$), then the disclosure is made if and only if consumers are in fact at risk. Then, a consumer who discovers the warning knows for sure that the product is not safe. On the other hand, when $r < a_0$ a warning message does not imply that the product is unsafe. A more precise disclosure standard (r closer to a_0) is more informative, and this should motivate consumers to spend more reading effort.

From the firm's perspective, the overall impact of a more precise disclosure standard is less clear. On the one hand, a higher r decreases firm level of care directly because the firm discloses less often. On the other hand, it induces consumers to spend more time and effort on inspecting the warning. Given that firm care is a strategic complement to consumer care, this indirectly increases firm care. If product liability is sufficiently weak, the direct effect on firm care is dominated by the indirect effect through consumer care; thus, the overall effect of a higher disclosure standard on firm care is positive. The effects of a more precise disclosure standard r are shown in Figure 2.8.

Figure 2.8: More Precise Disclosure Standard



Proposition 6. *A more precise disclosure standard (higher r) results in a higher equilibrium consumer care. Firm care tends to increase as well, which implies that the expected consumer utility increases and the expected harm declines.*

In equilibrium, consumers prefer the mandated disclosure standard to reflect the actual tolerance level. At the same time, the impact of a higher disclosure standard on firm's profits is ambiguous. On the one hand, a higher r decreases the probability that the warning is posted when the product is safe, which increases the demand. On the other hand, a higher r boosts consumer reading effort, which results in a lower demand.

Finally, a more precise disclosure standard decreases the expected harm. A higher r induces consumers to inspect warning labels more attentively and stimulates the manufacturer to respond with a higher level of care. Both of these effects result in a decrease in the expected harm.

Comparing Policy Tools

The policies that we considered in this paper are compared in Table 2.1 with respect to their effects on the equilibrium market outcome. The first column lists a set of policy tools, including strength of the liability system l , visibility of the warning message b , consumer risk perception λ , and precision of the disclosure standard r . Columns (2) through (6) indicate how a certain policy (e.g. a more visible warning message) affects the equilibrium consumer and firm care, firm's profits, consumers' expected utility, and expected harm. Negative or positive signs denote a corresponding negative or positive impact of a policy on a target outcome, and a question mark indicates an ambiguous overall effect of a policy. All the results hold for the sufficiently weak liability rule l , sufficiently low warning visibility b , and sufficiently high consumer susceptibility to allergens τ .

Table 2.1: Policy Implications: The Equilibrium Effects on Stakeholders

Policy Tool	Consumer Care (x_E^*)	Firm Care (y_E^*)	Expected Utility (EU)	Profits (π)	Expected Harm (H)
Higher Liability (l)	-	+	?	?	?
Higher Visibility (b)	+	+	+	-	-
Higher Risk Perception (λ)	+	+	+	-	-
Higher Disclosure Standard (r)	+	+	+	?	-

Our results demonstrate that policies targeted at boosting consumer care and firm care may have different implications. From the firm's prospective, firm care is a strategic complement to consumer reading effort. This means that a firm exerts more care if consumers spend more time and effort on inspecting labels. At the same time, from the consumer prospective, consumer reading effort is a strategic substitute to firm care, implying that an increase in firm care results in lower reading effort. Thus, if policymakers target firm care, they need to consider the negative effect on consumer care and recognize that the overall impact of such a policy on the expected harm can be

ambiguous. For example, a stronger product liability shifts the burden of care from consumers to firms, increasing firm care and reducing consumer care, with an ambiguous effect on the expected harm.

If policymakers target consumer care instead, then there is an additional indirect benefit: a policy that stimulates consumers to spend more time reading warning messages also stimulates the firm to provide a higher level of care and a safer product. For example, a higher visibility of warning labels reduces the expected harm directly and by inducing higher levels of firm and consumer care.

Among various policy tools, the precision of disclosure standard r deserves special attention. According to the existing requirements for labeling allergens in packaged food, a firm needs to notify consumers about any amount of harmful ingredients in their products. This disclosure rule implies that a warning needs to be posted on the label regardless of the actual amount of allergens or potential harm to consumer health. This reduces the informational value of the warning label, discourages consumers from spending time and effort on inspecting warning labels, and may not create additional incentives for the firm to exert a higher level of care. Our analysis suggests that disclosure standards tailored to specific tolerance levels for different allergens should reduce allergy-related healthcare costs.

We also find that the existing policies can hardly be appealing to everyone. Higher visibility of a warning message b boosts the expected consumer utility. At the same time, it reduces firm's profit. A more precise disclosure standard r increases the expected consumer utility, and has an ambiguous effect on the firm's profit. This suggests that the optimal policy choice depends on the weights assigned to firm and consumer gains. At the same time, all the policies we have considered, except for higher liability, tend to reduce the expected harm from a product if the liability system is sufficiently weak. In contrast, higher liability shifts the burden of care from consumers to producers, with unclear effects on the the expected harm.

Conclusion

There is a general consensus that market failures due to asymmetric information about product risks can be corrected by either regulation or litigation efforts. The main debate is over which tools should be used and how to design the best policy. This paper analyzes the interactive effects of regulation and litigation. In our model, a firm chooses a level of care that stochastically determines the safety level of the product. The optimum level of firm care depends on several factors, including legal and regulatory environment and consumer care – the effort they spend on reading and understanding warning labels posted by the firm. At the same time, consumer care is endogenous. It is determined by a set of factors, including the strength of liability and firm care.

From the consumer perspective, firm and consumer care levels are strategic substitutes, while for the firm they are strategic complements, provided that product liability is sufficiently weak. We find that a higher warning visibility and higher consumer risk perception increase the equilibrium consumer and firm care and, thus, decrease the expected harm. By contrast, stronger product liability shifts the burden of care from consumers to the firm. This increases the firm care and reduces consumer care, with an ambiguous effect on the expected harm.

Another reason why product liability may not be as powerful as regulation is that the good is a credence good. For experience goods, which we consider in this paper, consumers are the parties who actually suffer from harm, and they should have better information than the regulators about the source and the extent of the harm. Therefore, consumers are the most appropriate enforcement agents, suggesting the desirability of the liability tool. For credence goods, victims can hardly ascertain the risks associated with a product even after consuming it. In these cases, the use of the regulation could be advantageous.

This work can be further extended in a number of ways. We could allow for consumer het-

erogeneity in consumer susceptibility to product risks. Then, consumer participation in the market will be endogenously determined. That is, there will be a threshold level of susceptibility such that only consumers with lower levels of sensitivity would choose to participate in the market. We conjecture that the main results of this paper would continue to hold as long as the consumer response on the intensive margin (reading effort) dominates that on the extensive margin (decision to enter the market). It would be also interesting to study how litigation and regulation efforts interact when there is competition in the market.

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Appendix 2.A: Proofs

Proof of Proposition 1. For a consumer of type $\tau > \tau_D$, the interior optimal consumer reading effort x^* is determined by the first-order condition:

$$\frac{\partial EU(x^*)}{\partial x} = 0 = -c + B \frac{\partial f(x^*, b)}{\partial x}. \quad (2.15)$$

Inequality $\tau > \tau_D$ is equivalent to $B = P^e(y, a_0)\tau C - P^e(y, r)(v - p) > 0$ because $\tau_D \equiv \frac{v-p}{C} \frac{P^e(y, r)}{P^e(y, a_0)}$.

The second-order sufficient condition holds because $B > 0$ and $\frac{\partial^2 f}{\partial x^2} < 0$. Since we assume that discovery function is such that $\frac{\partial f(x, b)}{\partial x} \rightarrow 0$ as $x \rightarrow \infty$ and $\frac{\partial f(x, b)}{\partial x} \rightarrow \infty$ as $x \rightarrow 0$, it follows that there exists a unique interior optimal consumer reading effort $x^* > 0$.

Let z be any parameter $z \in \{y, b, r, v, p, a_0, \tau, h, C, \lambda, c\}$. Fully differentiating the first-order condition with respect to z , we obtain

$$\frac{\partial x^*}{\partial z} = -\frac{\frac{\partial^2 EU}{\partial x \partial z}}{\frac{\partial^2 EU}{\partial x^2}}. \quad (2.16)$$

Since by the second-order condition, $\frac{\partial^2 EU}{\partial x^2} < 0$ at x^* , the sign of $\frac{\partial x^*}{\partial z}$ is the same as the sign of $\frac{\partial^2 EU}{\partial x \partial z}$. First, note that $\frac{\partial^2 EU}{\partial x \partial c} = -1 < 0$, and thus $\frac{\partial x^*}{\partial c} < 0$. Second, $\frac{\partial^2 EU}{\partial x \partial b} = B \frac{\partial^2 f}{\partial x \partial b} > 0$, and thus $\frac{\partial x^*}{\partial b} > 0$. Other parameters affect the marginal expected utility by changing the benefit B of discovery: $\frac{\partial^2 EU}{\partial x \partial z} = \frac{\partial B}{\partial z} \frac{\partial f}{\partial x}$. For these parameters, the direction of comparative statics results follow from $\text{sign}\left(\frac{\partial x^*}{\partial z}\right) = \text{sign}\left(\frac{\partial B}{\partial z}\right)$. We find that $\frac{\partial B}{\partial(v-p)} = -P^e(y, r) < 0$, $\frac{\partial B}{\partial a_0} = \frac{\partial P^e(y, a_0)}{\partial a_0} \tau C < 0$, $\frac{\partial B}{\partial r} = -(v-p) \frac{\partial P^e(y, r)}{\partial r} > 0$, $\frac{\partial B}{\partial(\tau C)} = P^e(y, a_0) > 0$, and $\frac{\partial B}{\partial \lambda} > 0$. If $C = h(1-l) > 0$, then $\frac{\partial x^*}{\partial l} < 0$ and $\frac{\partial x^*}{\partial l} < 0$.

Finally, $\frac{\partial^2 EU}{\partial x \partial y} = \frac{\partial B}{\partial y} \frac{\partial f}{\partial x} < 0$ if $\frac{\partial B}{\partial y} = \tau C \frac{\partial P^e(y, a_0)}{\partial y} - (v-p) \frac{\partial P^e(y, r)}{\partial y} < 0$. This happens when regulation is sufficiently precise (r is close to a_0), τ is high (for $\tau > \hat{\tau} = \frac{v-p}{C} \frac{\frac{\partial P^e(y, r)}{\partial y}}{\frac{\partial P^e(y, a_0)}{\partial y}}$), or the uncompensated cost $C = (1-l)h$ is large (which tends to be the case when liability l is weak). Q.E.D.

Proof of Proposition 2. Firm's profits are

$$\pi = (p - m(y)) \times D(x, y) - lH(x, y) \quad (2.17)$$

$$= \pi_0 - \beta f(x, b), \quad (2.18)$$

where $\pi_0 \equiv [p - m(y) - lh\tau P(y, a_0)]$ is the profit from selling the product to consumers who do not read labels and $\beta \equiv (p - m(y))P(y, r) - lh\tau P(y, a_0)$ is the profit loss from a reduction in consumer demand due to consumer reading of warning labels. We find that $\beta > 0$ for sufficiently weak liability $l < l_1$, where $l_1 \equiv \frac{(p-m(y))}{h\tau} \frac{P(y,r)}{P(y,a_0)} > 0$.

Assuming that there exists an interior solution for the optimal firm care, it is described by the first-order condition

$$\frac{\partial \pi}{\partial y} = \frac{\partial \pi_0}{\partial y} - \frac{\partial \beta}{\partial y} f(x, b) = 0, \quad (2.19)$$

where $\frac{\partial \beta}{\partial y} = -m'(y)P(y, r) + (p - m(y)) \frac{\partial P(y, r)}{\partial y} - lh\tau \frac{\partial P(y, a_0)}{\partial y}$. Note that $\frac{\partial \pi}{\partial x} = -\beta \frac{\partial f}{\partial x}$ and since $\beta > 0$ for $l < l_1$, the firm prefers lower levels of consumer reading effort, $\frac{\partial \pi}{\partial x} < 0$. We find that $\frac{\partial \beta}{\partial y} < 0$ for $l < l_2$, where $l_2 \equiv \frac{m'(y)P(y,r) + (p-m(y)) \left(-\frac{\partial P(y,r)}{\partial y} \right)}{h\tau \left(-\frac{\partial P(y,a_0)}{\partial y} \right)} > 0$.

Let z be any parameter $z \in \{x, l, b, r, p, \tau, h\}$. Fully differentiating the first-order condition for firm care with respect to z , we obtain

$$\frac{\partial y^*}{\partial z} = -\frac{\frac{\partial^2 \pi}{\partial y \partial z}}{\frac{\partial^2 \pi}{\partial y^2}}. \quad (2.20)$$

Since by the second-order condition, $\frac{\partial^2 \pi}{\partial y^2} < 0$ at y^* , the sign of $\frac{\partial y^*}{\partial z}$ is the same as the sign of $\frac{\partial^2 \pi}{\partial y \partial z}$.

Since $\frac{\partial^2 \pi}{\partial x \partial y} = -\frac{\partial \beta}{\partial y} \frac{\partial f}{\partial x} > 0$, we find that $\frac{\partial y^*}{\partial x} > 0$ for sufficiently low l . It always holds if the regulation exact ($r = a_0$). Similarly, for $l < l_2$, $\frac{\partial^2 \pi}{\partial b \partial y} = -\frac{\partial \beta}{\partial y} \frac{\partial f}{\partial b} > 0$ and $\frac{\partial y^*}{\partial b} > 0$. We find that the following second-order cross-partial derivatives are always positive:

$$\begin{aligned}\frac{\partial^2 \pi}{\partial l \partial y} &= -h\tau \frac{\partial P(y, a_0)}{\partial y} (1 - f(x, b)) > 0 \\ \frac{\partial^2 \pi}{\partial p \partial y} &= -\frac{\partial P(y, r)}{\partial y} f(x) > 0\end{aligned}\quad (2.21)$$

Hence, y^* is increasing in l (and similarly in h and τ) and p .

Finally, the effect of r on y^* depends on the shape of $P(y, r)$: $\frac{\partial^2 \pi}{\partial r \partial y} = -\frac{\partial^2 \beta}{\partial r \partial y} f(x, b) < 0$ whenever $\frac{\partial^2 \beta}{\partial r \partial y} = (p - m(y)) \frac{\partial^2 P(y, r)}{\partial r \partial y} - m'(y) \frac{\partial P(y, r)}{\partial r} > 0$. Q.E.D.

Proof of Proposition 3. The following expressions quantify the effects of l on the equilibrium levels of care:

$$\begin{aligned}\frac{dx_E^*}{dl} &= \frac{\frac{\partial^2 EU}{\partial l \partial x} \frac{\partial^2 \pi}{\partial y^2} - \frac{\partial^2 EU}{\partial x \partial y} \frac{\partial^2 \pi}{\partial l \partial y}}{\frac{\partial^2 EU}{\partial x \partial y} \frac{\partial^2 \pi}{\partial x \partial y} - \frac{\partial^2 EU}{\partial x^2} \frac{\partial^2 \pi}{\partial y^2}} \\ &= \frac{\left\{ \frac{\partial^2 EU}{\partial l \partial x} \right\} (SOC_y) - \left[\frac{\partial^2 EU}{\partial x \partial y} \right] \left\{ \frac{\partial^2 \pi}{\partial l \partial y} \right\}}{\left[\frac{\partial^2 EU}{\partial x \partial y} \right] \left[\frac{\partial^2 \pi}{\partial x \partial y} \right] - (SOC_x) (SOC_y)} \\ &= \frac{\{-\}(-) - [-]\{+\}}{[-][+] - (-)(-)} = \frac{+}{-} < 0\end{aligned}\quad (2.22)$$

and

$$\begin{aligned}\frac{dy_E^*}{dl} &= \frac{\frac{\partial^2 \pi}{\partial l \partial y} \frac{\partial^2 EU}{\partial x^2} - \frac{\partial^2 \pi}{\partial x \partial y} \frac{\partial^2 EU}{\partial l \partial x}}{\frac{\partial^2 \pi}{\partial x \partial y} \frac{\partial^2 EU}{\partial x \partial y} - \frac{\partial^2 \pi}{\partial y^2} \frac{\partial^2 EU}{\partial x^2}} \\ &= \frac{\left\{ \frac{\partial^2 \pi}{\partial l \partial y} \right\} (SOC_x) - \left[\frac{\partial^2 \pi}{\partial x \partial y} \right] \left\{ \frac{\partial^2 EU}{\partial l \partial x} \right\}}{\left[\frac{\partial^2 \pi}{\partial x \partial y} \right] \left[\frac{\partial^2 EU}{\partial x \partial y} \right] - (SOC_y) (SOC_x)} \\ &= \frac{\{+\}(-) - [+]\{-\}}{[+][-] - (-)(-)} = \frac{?}{-}\end{aligned}\quad (2.23)$$

We find that $\frac{dx_E^*}{dl} < 0$. Also, $\frac{dy_E^*}{dl} > 0$ under the following condition:

$$\frac{\partial^2 \pi}{\partial l \partial y} > \frac{\left\{ \frac{\partial^2 EU}{\partial l \partial x} \right\}}{\left[\frac{\partial^2 \pi}{\partial x \partial y} \right] (SOC_x)}.\quad (2.24)$$

Using $\left\{ \frac{\partial^2 EU}{\partial l \partial x} \right\} = \frac{\partial B}{\partial l} \frac{\partial f}{\partial x} = -P^e(y, a_0) h \tau \frac{\partial f}{\partial x} < 0$, $\left[\frac{\partial^2 \pi}{\partial x \partial y} \right] = -\frac{\partial \beta}{\partial y} \frac{\partial f}{\partial x}$, $(SOC_x) = B \frac{\partial^2 f}{\partial x^2} < 0$, and

$\frac{\partial^2 \pi}{\partial l \partial y} = -h\tau \frac{\partial P(y, a_0)}{\partial y} (1 - f(x, b)) > 0$, we can rewrite the inequality as

$$(1 - f) \left(-\frac{\partial^2 f}{\partial x^2} \right) > \frac{\frac{\partial B}{\partial l}}{B \frac{\partial \beta}{\partial y} \left(-\frac{\partial P(y, a_0)}{\partial y} \right)} \quad (2.25)$$

where $\frac{\partial \beta}{\partial y} = -m'(y)P(y, r) + (p - m(y)) \frac{\partial P(y, r)}{\partial y} - lh\tau \frac{\partial P(y, a_0)}{\partial y} < 0$ for $l < l_2$, $B = P^e(y, a_0)\tau h(1 - l) - P^e(y, r)(v - p)$, and $\frac{\partial B}{\partial l} = -P^e(y, a_0)\tau h < 0$. Note that the RHS of the inequality does not depend on x and b , while the LHS depend on x and b but not on y . Suppose visibility $b \rightarrow 0$. Then, $x \rightarrow 0$ and the LHS of the inequality grows large because $f(x, b) \rightarrow 0$ and $\frac{\partial^2 f}{\partial x^2} \rightarrow -\infty$ as $b \rightarrow 0$ and $x \rightarrow 0$. Q.E.D.

Proof of Proposition 4. The following expressions quantify the effects of b on the equilibrium levels of care:

$$\begin{aligned} \frac{dx_E^*}{db} &= \frac{\frac{\partial^2 EU}{\partial b \partial x} \frac{\partial^2 \pi}{\partial y^2} - \frac{\partial^2 EU}{\partial x \partial y} \frac{\partial^2 \pi}{\partial b \partial y}}{\frac{\partial^2 EU}{\partial x \partial y} \frac{\partial^2 \pi}{\partial x \partial y} - \frac{\partial^2 EU}{\partial x^2} \frac{\partial^2 \pi}{\partial y^2}} \quad (2.26) \\ &= \frac{\left\{ \frac{\partial^2 EU}{\partial b \partial x} \right\} (SOC_y) - \left[\frac{\partial^2 EU}{\partial x \partial y} \right] \left\{ \frac{\partial^2 \pi}{\partial b \partial y} \right\}}{\left[\frac{\partial^2 EU}{\partial x \partial y} \right] \left[\frac{\partial^2 \pi}{\partial x \partial y} \right] - (SOC_x) (SOC_y)} \\ &= \frac{\{+\}(-) - [-]\{+\}}{[+][-] - (-)(-)} = \frac{?}{-} \end{aligned}$$

$$\begin{aligned} \frac{dy_E^*}{db} &= \frac{\frac{\partial^2 \pi}{\partial b \partial y} \frac{\partial^2 EU}{\partial x^2} - \frac{\partial^2 \pi}{\partial x \partial y} \frac{\partial^2 EU}{\partial b \partial x}}{\frac{\partial^2 \pi}{\partial x \partial y} \frac{\partial^2 EU}{\partial x \partial y} - \frac{\partial^2 \pi}{\partial y^2} \frac{\partial^2 EU}{\partial x^2}} \quad (2.27) \\ &= \frac{\left\{ \frac{\partial^2 \pi}{\partial b \partial y} \right\} (SOC_x) - \left[\frac{\partial^2 \pi}{\partial x \partial y} \right] \left\{ \frac{\partial^2 EU}{\partial b \partial x} \right\}}{\left[\frac{\partial^2 \pi}{\partial x \partial y} \right] \left[\frac{\partial^2 EU}{\partial x \partial y} \right] - (SOC_y) (SOC_x)} \\ &= \frac{\{+\}(-) - [+]\{+\}}{[+][-] - (-)(-)} = \frac{-}{-} > 0 \end{aligned}$$

Therefore, we find that $\frac{dx_E^*}{db} > 0$ under the following condition:

$$\frac{\partial^2 EU}{\partial b \partial x} > \left[\frac{\partial^2 EU}{\partial x \partial y} \right] \left\{ \frac{\partial^2 \pi}{\partial b \partial y} \right\} / (SOC_y)$$

Recalling that $\left\{ \frac{\partial^2 EU}{\partial b \partial x} \right\} = B \frac{\partial^2 f}{\partial x \partial b} > 0$, $(SOC_y) = \left(\frac{\partial^2 \pi}{\partial y^2} \right) = -m''(y) - lh\tau \frac{\partial^2 P(y, a_0)}{\partial y^2} - \frac{\partial^2 \beta}{\partial y^2} f(x, b) < 0$, $\left[\frac{\partial^2 EU}{\partial x \partial y} \right] = \frac{\partial B}{\partial y} \frac{\partial f}{\partial x} < 0$ for $\tau > \hat{\tau}$, and $\left\{ \frac{\partial^2 \pi}{\partial b \partial y} \right\} = -\frac{\partial \beta}{\partial y} \frac{\partial f}{\partial b} > 0$ for $l < l_2$. We can re-write the condition as

$$\frac{\frac{\partial^2 f}{\partial x \partial b}}{\frac{\partial f}{\partial x} \frac{\partial f}{\partial b}} > \frac{\frac{\partial B}{\partial y} \left(-\frac{\partial \beta}{\partial y} \right)}{B \left(\frac{\partial^2 \pi}{\partial y^2} \right)}.$$

Assume this holds. This would be true, for example, when visibility is sufficiently low and $f(x, b) = bx^\alpha$. Note that in this case, $\frac{\frac{\partial^2 f}{\partial x \partial b}}{\frac{\partial f}{\partial x} \frac{\partial f}{\partial b}} = \frac{1}{f(x, b)} \rightarrow \infty$ as $b \rightarrow 0$, while the RHS of the inequality is remains bounded as $b \rightarrow 0$.

Then,

$$\frac{dH}{db} = \frac{\partial H}{\partial b} + \frac{\partial H}{\partial x} \frac{dx_E^*}{db} + \frac{\partial H}{\partial y} \frac{dy_E^*}{db} < 0, \quad (2.28)$$

where $\frac{\partial H}{\partial b} < 0$, $\frac{\partial H}{\partial x} < 0$, $\frac{dx_E^*}{db} > 0$ under a sufficiently weak liability standard l , $\frac{\partial H}{\partial y} < 0$, and $\frac{dy_E^*}{db} > 0$.

In equilibrium, consumers favor more visible warnings:

$$\frac{dEU}{db} = \frac{\partial EU}{\partial b} + \frac{\partial EU}{\partial y} \frac{dy_E^*}{db} > 0, \quad (2.29)$$

where $\frac{\partial EU}{\partial b} > 0$, $\frac{\partial EU}{\partial y} > 0$, and $\frac{dy_E^*}{db} > 0$. The firm prefers that consumers spend less time reading labels, $\frac{\partial \pi}{\partial x} < 0$. Then, the overall impact of higher visibility on firm profits is negative:

$$\frac{d\pi}{db} = \frac{\partial \pi}{\partial b} + \frac{\partial \pi}{\partial x} \frac{dx_E^*}{db} < 0, \quad (2.30)$$

where $\frac{\partial \pi}{\partial b} = -\beta \frac{\partial f}{\partial b} < 0$, $\frac{\partial \pi}{\partial x} = -\beta \frac{\partial f}{\partial x} < 0$, and $\frac{dx_E^*}{db} > 0$ under a sufficiently weak liability standard l .

Q.E.D.

Proof of Proposition 5.

From Proposition 1, $\frac{\partial x^*}{\partial \lambda} > 0$. Since $\frac{\partial y^*}{\partial \lambda} = 0$, $\frac{dx_E^*}{d\lambda} > 0$ and $\frac{dy_E^*}{d\lambda} > 0$. The following expressions

quantify the effects of r on the equilibrium levels of care:

$$\frac{dx_E^*}{d\lambda} = \frac{\frac{\partial^2 EU}{\partial \lambda \partial x} \frac{\partial^2 \pi}{\partial y^2}}{\frac{\partial^2 EU}{\partial x \partial y} \frac{\partial^2 \pi}{\partial x \partial y} - \frac{\partial^2 EU}{\partial x^2} \frac{\partial^2 \pi}{\partial y^2}} = \frac{-}{-} > 0$$

$$\frac{dy_E^*}{d\lambda} = \frac{-\frac{\partial^2 \pi}{\partial x \partial y} \frac{\partial^2 EU}{\partial \lambda \partial x}}{\frac{\partial^2 \pi}{\partial x \partial y} \frac{\partial^2 EU}{\partial x \partial y} - \frac{\partial^2 \pi}{\partial y^2} \frac{\partial^2 EU}{\partial x^2}} = \frac{-}{-} > 0$$

Then, higher λ results in a lower expected harm:

$$\frac{dH}{d\lambda} = \frac{\partial H}{\partial x} \frac{dx_E^*}{d\lambda} + \frac{\partial H}{\partial y} \frac{dy_E^*}{d\lambda} < 0. \quad (2.31)$$

The overall impact of λ on firm profits is negative:

$$\frac{d\pi}{d\lambda} = \frac{\partial \pi}{\partial x} \frac{dx_E^*}{d\lambda} < 0 \quad (2.32)$$

because $\frac{\partial \pi}{\partial x} < 0$. Q.E.D.

Proof of Proposition 6. The following expressions quantify the effects of r on the equilibrium levels of care:

$$\begin{aligned} \frac{dx_E^*}{dr} &= \frac{\frac{\partial^2 EU}{\partial r \partial x} \frac{\partial^2 \pi}{\partial y^2} - \frac{\partial^2 EU}{\partial x \partial y} \frac{\partial^2 \pi}{\partial r \partial y}}{\frac{\partial^2 EU}{\partial x \partial y} \frac{\partial^2 \pi}{\partial x \partial y} - \frac{\partial^2 EU}{\partial x^2} \frac{\partial^2 \pi}{\partial y^2}} \quad (2.33) \\ &= \frac{\left\{ \frac{\partial^2 EU}{\partial r \partial x} \right\} (SOC_y) - \left[\frac{\partial^2 EU}{\partial x \partial y} \right] \left\{ \frac{\partial^2 \pi}{\partial r \partial y} \right\}}{\left[\frac{\partial^2 EU}{\partial x \partial y} \right] \left[\frac{\partial^2 \pi}{\partial x \partial y} \right] - (SOC_x) (SOC_y)} \\ &= \frac{\{+\}(-) - [-]\{-\}}{[-][+] - (-)(-)} > 0 \end{aligned}$$

$$\begin{aligned}
\frac{dy_E^*}{dr} &= \frac{\frac{\partial^2 \pi}{\partial r \partial y} \frac{\partial^2 EU}{\partial x^2} - \frac{\partial^2 \pi}{\partial x \partial y} \frac{\partial^2 EU}{\partial r \partial x}}{\frac{\partial^2 \pi}{\partial x \partial y} \frac{\partial^2 EU}{\partial x \partial y} - \frac{\partial^2 \pi}{\partial y^2} \frac{\partial^2 EU}{\partial x^2}} \\
&= \frac{\left\{ \frac{\partial^2 \pi}{\partial r \partial y} \right\} (SOC_x) - \left[\frac{\partial^2 \pi}{\partial x \partial y} \right] \left\{ \frac{\partial^2 EU}{\partial r \partial x} \right\}}{\left[\frac{\partial^2 \pi}{\partial x \partial y} \right] \left[\frac{\partial^2 EU}{\partial x \partial y} \right] - (SOC_y) (SOC_x)} \\
&= \frac{\{-\}(-) - \{+\}\{+\}}{\{+\}\{-\} - (-)(-)} = \frac{?}{-}
\end{aligned} \tag{2.34}$$

We find that $\frac{dy_E^*}{dr} > 0$ under the following condition:

$$\left(-\frac{\partial^2 \pi}{\partial r \partial y} \right) > \left[\frac{\partial^2 \pi}{\partial x \partial y} \right] \left\{ \frac{\partial^2 EU}{\partial r \partial x} \right\} / |(SOC_x)|$$

Recall that $\frac{\partial^2 \pi}{\partial r \partial y} = -\frac{\partial^2 \beta}{\partial r \partial y} f(x, b) < 0$, $\frac{\partial^2 EU}{\partial r \partial x} = \frac{\partial B}{\partial r} \frac{\partial f}{\partial x} = -\frac{\partial P(y, r)}{\partial r} (v - p) \frac{\partial f}{\partial x} > 0$, $(SOC_x) = \left(\frac{\partial^2 EU}{\partial x^2} \right) = B \frac{\partial^2 f}{\partial x^2} < 0$, and $\left[\frac{\partial^2 \pi}{\partial x \partial y} \right] = -\frac{\partial \beta}{\partial y} \frac{\partial f}{\partial x} > 0$. Assume that the inequality holds, and therefore $\frac{dy_E^*}{dr} > 0$.

Then, consumers prefer the mandated disclosure standard to reflect the actual tolerance level:

$$\frac{dEU}{dr} = \frac{\partial EU}{\partial r} + \frac{\partial EU}{\partial y} \frac{dy_E^*}{dr} > 0, \tag{2.35}$$

where $\frac{\partial EU}{\partial r} = \frac{\partial B}{\partial r} f(x, b) = \left(-\frac{\partial P^e(y, r)}{\partial r} \right) (v - p) f(x, b) > 0$ and $\frac{\partial EU}{\partial y} > 0$.

At the same time, the impact of a higher disclosure standard on firm profit is ambiguous. On the one hand, a higher r decreases the probability that the warning is posted when the product is safe. This increases the demand. On the other hand, a higher r boosts consumer reading effort, which results in lower demand. The marginal effect of higher r on equilibrium profit of the firm is

$$\frac{d\pi}{dr} = \frac{\partial \pi}{\partial r} + \frac{\partial \pi}{\partial x} \frac{dx_E^*}{dr}, \tag{2.36}$$

where $\frac{\partial \pi}{\partial r} = -\frac{\partial \beta}{\partial r} f(x, b) = (p - m(y)) \left(-\frac{\partial P(y, r)}{\partial r} \right) f(x, b) > 0$, $\frac{\partial \pi}{\partial x} < 0$, and $\frac{dx_E^*}{dr} > 0$. Therefore, profits could be higher or lower depending on the relative size of the terms.

Finally, a weaker disclosure standard decreases the expected harm from a risky product. Higher r induces consumers to inspect the warning more attentively and stimulates the manufacturer to respond with a higher level of care. Both of these effects result in a decrease in the expected harm:

$$\frac{dH}{dr} = \frac{\partial H}{\partial x} \frac{dx_E^*}{dr} + \frac{\partial H}{\partial y} \frac{dy_E^*}{dr} < 0, \quad (2.37)$$

where $\frac{\partial H}{\partial x} < 0$, $\frac{dx_E^*}{dr} > 0$, $\frac{\partial H}{\partial y} < 0$, and $\frac{dy_E^*}{dr} > 0$ under a sufficiently weak liability l . Q.E.D.

CHAPTER 3

CONSUMER ATTENTION TO HEALTH WARNINGS:

DOES THE REFERENCE RISK MATTER?

Abstract

This paper analyzes if consumers' reaction to health warnings depends on their susceptibility to the risk. I use a difference-in-differences methodology and a two-step setup to evaluate disclosure of the major food allergens on product labels and to contrast impact of the policy on consumers with the higher and lower allergen sensitivity. Perhaps surprisingly, the policy improves health outcomes of patients with lower allergen susceptibility. However, when controlling for the exogenous variation in patients' prior expectations about product safety, I find no difference in reactions to warning messages regardless of consumers' allergen sensitivity. Comparison of the "mass" regulatory initiatives and personalized warnings favors the latter and shows no link between the mass campaigns and health improvements unless consumers have access to individualized allergy warnings.

Introduction

The major focus of a risk information campaign is to correct the asymmetric awareness of sellers and buyers about the safety level of a product. Recently the public is overwhelmed with warnings about health, safety, and environmental hazards (Greenstone and Gallagher, 2008; Viscusi, 2007). Consumers are notified of carcinogenic additives in their yogurt, warned of the environmental and toxicological effects of GMO crops, and bombarded with side effects of drugs and alcohol. Some of the risk information campaigns proved to have disappointing effects on consumer safety, with high teenage drunken driving rates to be among the leading examples (Viscusi, 2007). This calls for identifying the limitations that hamper consumers' ability to respond to the warnings.

The goal of this paper is to understand if consumers' reaction to health warnings depends on their susceptibility to the risk, and, if so, to determine what demand segments are affected the most by the information campaigns. Recent literature concludes that the market responds more to bad news than to good news, since bad news require higher standard of evidence. However, the majority of papers addressing this issue either document the asymmetric response as such (Greenstone et al., 2008; Beaver et al., 2006; Gayer et al., 2002; Kliger et al., 2000) or analyze the optimum timing to disclose negative information (Dranove and Jin, 2010; DellaVigna and Pollet, 2009). A limited number of papers recognize that consumer response differs by susceptibility. Consumers with higher sensitivity to the risk are less likely to bare the risk; therefore, they express higher incremental willingness to pay for risk reduction (Jin et al., 2006; Viscusi et al., 2005, 1987). Thus, for a given price-quality combination, these consumers might be *more* likely to notice the warning and to spend more time and effort on inspecting the message. Alternatively, consumers with higher reference risk might benefit *less* from disclosure of health risks if in pre-intervention period they have more adequate prior about product quality (Dranove and Sfekas, 2008; Dafny and Dranove,

2008). Finally, studies analyzing addictive behavior document a similar effect of the risk information on both categories of consumers (Smith et al., 2001; Viscusi, 1991). However, it is not clear if this result is driven by the addictiveness.

This paper aims at resolving existing ambiguities, and it contributes to the literature in a number of ways. First, it focuses on *consumer* reaction to health warnings and abstracts from other factors, including willingness of manufacturers to disclose risk information, legislative environment, market structure etc. To do so, I contrast consumers with higher and lower susceptibility to the risk. In this setting, both groups of customers are exposed to the same health warnings, which are disclosed at the same time, have the same clarity and relevance, related to the same goods having a given price, and pertain to the same market. Therefore, different reaction to risk warnings between consumers with higher and lower susceptibility to the risk would be solely due to the difference in *consumers' susceptibility* of the risk. Second, this paper evaluates the impact of consumers' prior information on their ability to react to risk warnings. In the case of food allergies, consumers with the higher reference risk are notified by medical practitioners about a full set of foods containing harmful allergens, which affect a patient directly or cross-react with allergens a patient is sensitive to, and the patients are strictly advised to eliminate all these products. Patients with the *lower* reference risk are notified predominantly of the allergens affecting a patient directly. Additionally, doctors do not see the need in dietary restrictions for this category of patients (NIH NIAID, 2011) or (Sicherer, 2011; Kurowski et al., 2008; Bischoff, 2007). As a result, consumers with the higher reference risk have better prior information about their disease. This prior does not result from patients' desire to learn more, but it is exogenously determined by doctors' willingness to share more information. This quasi-experiment creates a unique opportunity to evaluate the role of consumers' prior information and to measure its impact on consumers' decisions to avoid risks. Additionally, this paper examines different modes of expressing risk information and compares the mass risk

information campaigns, initiated by industry or regulatory agencies, to personalized risk warnings, effective in a pre-public campaign era. This allows determining policy tools that are the most efficient in targeting consumers with different risk sensitivity.

As an example of the risk information campaign, I focus on food allergen labeling initiatives that stress the need to label eight major allergens responsible for 90 percent of all food allergies. Food allergen labeling is a unique example to evaluate risk information campaigns. In contrast to other diseases, vulnerable patients experience allergic reactions within a couple of hours after their contact with an allergen. This allows analyzing the *immediate* effect of a policy. Additionally, epidemiological literature documents a limited cure for allergies, and advises to manage the disease predominantly by avoiding products that contain allergens. This allows to evaluate the *provision* of allergy warnings rather than medical advancements in treating the disease.

I evaluate the policy by examining its impact on morbidity of allergic consumers, and I analyze the variation in the number of patients with higher and lower allergen sensitivity in periods preceding and following the disclosure of allergen content on food labels. I define allergen susceptibility in two different ways. The National Hospital Ambulatory Medical Care Survey for 1997 – 2007 allows to contrast patients seeking medical help in emergency rooms (higher sensitivity to allergens) to those attending outpatient departments (lower risk sensitivity). HCUP State Emergency Department Dataset for the state of Maryland for 1999 – 2008 allows to zoom in on the symptoms of food allergies and to compare life-threatening and non-life threatening cases.

I demonstrate that risk information disclosure predominantly influences consumers with lower susceptibility to the risk. On the contrary, customers having higher risk sensitivity are affected to a lesser extent, regardless of the definition of allergen susceptibility and the modes of communicating the warnings. This may signify that consumers with higher allergens susceptibility have better prior information about harmful ingredients and, consequently, they are less sensitive to

incremental improvements in their prior, introduced by the industry and regulatory allergen warning campaigns.

I evaluate the impact of consumers' prior information by comparing the insured patients to the uninsured population for each allergen sensitivity types. Since the allergen information is provided by medical practitioners, insured patients have better access to the information prior to their current ER visit. I demonstrate that if we control for the exogenous variation in patients' prior, consumers react to allergen warnings similarly, regardless of their susceptibility to the risk.

Background

Food Allergen Labeling Regulation and Its Impact on Consumers

The goal of food allergen labeling legislation is to notify consumers about the major allergens responsible for 90 percent of all food allergies. The major motivation for this initiative is a sharp increase in the number of patients diagnosed with the disease during the last 15 years. Between 1997 and 2007 the incidence of food allergies among patients ages 18 and younger has doubled, and the number of hospitalizations increased by about 2.6 times ([Sakellariou et al., 2010](#); [Branum et al., 2009](#); [Venter et al., 2006](#)).

The food allergen labeling campaign was launched in April 2001, when the National Food Processors Association (NFPA) released its "Code of Practice" in collaboration with the FDA. This initiative was followed by the Federal "Food Allergen Labeling and Consumer Protection Act" (FALCPA), enacted in July 2004 and effective since January 2006. Both initiatives had similar requirements about displaying the allergen warnings on food labels. First, they called for listing the eight most common food allergens that account for about 90 of all food allergies, including milk, eggs, fish, Crustacean shellfish, tree nuts, peanut, wheat, and soybeans ([Fortin, 2006](#); [USDA, 2006](#); [Formanek, 2001](#)). Second, they required listing of any amount of the major allergens, including

incidental and processing additives and allergens contained in colors and flavors. Third, they banned the use of Latin terminology, and necessitated listing the common name for allergic substances in "plain and clear English". The federal mandate further excelled in improving the visibility and clarity of food allergen labels (USDA, 2006). First, it banned fine prints. Second, it set uniform criteria for positioning the warning. It allowed to locate an allergen either immediately after an ingredient (e.g. "casein (milk)") or as a separate list following the list of the ingredients (e.g. "contains peanuts etc.").

However, consumers' ability to understand allergen warnings is compromised by several nuances. Both documents exempt raw meat, poultry, and egg products from labeling, all of which are regulated by the USDA's Food Safety and Inspection Service (FDA, 2009). Both initiatives extend only to retail and all food-service establishments and do not apply to foods placed in a wrapper, a carry-out box, or other container after being ordered by a consumer (USDA, 2006). These nuances confuse consumers unaware of the exemptions: a large proportion of allergic patients do not know that the legislation does not apply to unpacked food, and only 30 of customers correctly know that raw meat is exempt from labeling (Ahn et al., 2008; Vierk et al., 2007). Additionally, consumers might have had misperceptions about by the timing of FALCPA implementation. Even though the law went into effect in January 2006, the FDA did not require to re-label or recall foods manufactured prior to 2006 (FDA, 2009).

Regardless of these nuances, food allergen labeling initiatives of 2001 and 2006 were significant steps forward in providing allergic consumers with food quality information. Prior to 2001, food labeling was regulated by the Federal Food, Drug, and Cosmetic Act (*FD&C Act*) of 1938. This document did not restrict the use of unsafe food ingredients and allowed for some ambiguities in their labeling. First, it allowed for generic listing of colors and flavors (e.g. "natural flavoring") without specifying particular hidden allergens such as milk or soy protein (Fortin, 2006; Joshi

et al., 2002). Second, incidental or processing additives were exempt from labeling. For example, if lecithin was used to separate food from the equipment, it was not required to be mentioned on the label. Finally, the FDC Act did not prevent manufacturers from using ambiguous Latin terminology. For instance, wheat might be labeled as "semolina", and egg protein - as "albumin" (Munoz-Furlong, 2001). Label ambiguities and complex ingredient terminology could have compromised consumers' ability to comprehend the labels and to make inference about product safety.

Epidemiological literature documents that food allergen warnings are essential to allergic consumers. Ninety- nine percent of consumers having allergies read the labels on purchase, and 86 percent contact manufacturers for more information if the label is ambiguous (Noimark et al., 2009; Simons et al., 2005). The majority of allergic patients indicate that the labeling campaigns have significantly improved their awareness of the product safety. Prior to 2001, only 20 percent of patients with food allergies were able to correctly identify common allergens in food, while in the post-regulation period their number increased to 95 percent (Ahn et al., 2008; Joshi et al., 2002). Overall, the existing literature stresses the importance of allergen labeling, but it overlooks the impact of the policy on vulnerable consumers with different sensitivity to the message.

Consumers with Different Sensitivity to Allergens: Definition and Methodological Applications

Consumers' attention to allergen warnings may depend on the intensity of their allergic reactions. According to epidemiological studies, the intensity of reactions varies significantly, depending on the type of an allergen. Peanuts, tree nuts, fish and shellfish are reported to cause the most severe and life-threatening reactions ("life-threatening group"), whereas other ingredients - milk, eggs, wheat, and soybeans - cause milder allergies ("milder type").

Consumers, sensitive to "life-threatening" allergens, are documented to have immediate and intensive reactions that require urgent medical help: among patients admitted to emergency

rooms a median latent period between ingestion and symptoms equals to about 2 hours; among allergies resulted in fatalities it equals to about 15.4 minutes (Keet and Wood, 2007). In contrast to that, consumers sensitive to "milder" allergens have the limited need in medical assistance. In an extreme case, customers do not need medical help if symptoms of their disease can be mitigated by using general care remedies such as skin creams, eye drops, nasal sprays, vitamins, etc. (Proksch et al., 2008; Loden, 2005). Patients with moderate reactions to "milder" allergens feel the need for prescription or OTC medications, and they visit non-ER institutionalized medical practitioners to get or renew their prescription if the drugs are covered by their medical insurance (Petersen, 2002). Uninsured patients with the above average severity of their "milder" allergies might seek medical help. However, medical literature provides no evidence if they prefer to visit ER or non-ER facilities.

I hypothesize that the severity and urgency of food allergies determine patients' choice of a medical institution. "Life-threatening" allergies are most likely to be recorded in emergency rooms (ERs). Insured patients with "milder" symptoms are most likely to attend outpatient departments (OPDs)¹. Uninsured patients having non-life-threatening allergies with above-the-average severity might be recorded in both ERs and OPDs. Therefore, uninsured patients have to be dropped if I compare ER to OPD records as a representation of patients with the higher and lower allergen susceptibility. I also drop Medicaid patients, since in ER sample it is not clear if these patients got enrolled in Medicaid after they got admitted to an ER or prior to their visits.

As an alternative to comparing OPD and ER patients, I differentiate between "life-threatening" and "milder" cases by looking at allergy symptoms. In this case, I focus exclusively on ER visits, and incorporate the full set of ER patients, including uninsured and Medicaid patients ignored in the

¹Alternatively, these patients might choose to visit non-institutionalized medical practitioners. However, this hypothesis cannot be verified with the data. NAMCS, which provides nationally representative records from non-federal employed office-based physicians, contains few observations for any allergy types including food and non-food allergies.

previous scenario. The "life-threatening" allergens (peanuts, tree nuts, fish and shellfish) are most commonly manifested by anaphylaxis, with skin and respiratory systems to be among the most frequently affected organ systems. Skin manifestations are widely represented by urticaria and general flushing. The respiratory arrests are often accompanied by isolated cardiovascular symptoms that cause most of the fatalities (Keet and Wood, 2007). In contrast to "life-threatening" cases, "milder" allergens (milk, eggs, wheat, and soybeans) do not result in respiratory or cardiac collapse. These allergens cause weaker reactions, with atopic dermatitis, gastrointestinal symptoms and cutaneous symptoms (e.g. urticaria, flushing, and angioedema) to be the most common representations (Keet and Wood, 2007). Based on the epidemiological evidence, I extend the definition of "life-threatening" and "milder" allergies. The former includes allergy to peanuts, tree nuts, fish and seafood, as well as allergic respiratory reactions and anaphylactic shock due to food. The latter includes allergy to milk and to eggs ² as well as gastrointestinal symptoms. At the same time, dermatitis and cutaneous symptoms are excluded from this analysis, since they are associated with both allergy types (Table 3.1).

Data

I evaluate the impact of the allergen labeling campaigns on consumers with different susceptibility to risk by looking at morbidity of patients diagnosed with food allergies. I track the number of consumers seeking medical help and define patients with different sensitivity to allergens in two different ways. First, patients with higher sensitivity to allergens are defined as those seeking medical help in emergency rooms (ERs), while those with lower sensitivity to risk attend outpatient departments (OPDs). Second, I zoom in on the symptoms of food allergies and differentiate between "life-threatening" and "milder" cases that represent higher and lower allergen

²When I differentiate between "life-threatening" and "milder" cases based on allergy symptoms, I cannot incorporate allergies to soybeans and wheat, since they do not have a distinct ICD-9 code (Appendix 3.B).

sensitivity respectively (Table 3.1). In both cases, I evaluate the effect of an information campaign by tracking the number of visits with particular allergy sensitivity, and compare patients with higher risk sensitivity to those having lower reference risk.

I utilize two data sources. ER and OPD data files from the National Hospital Ambulatory Medical Care Survey (NHAMCS) provide nationally representative records of food allergies for 1997 – 2007. I use this dataset to analyze privately insured and Medicare patients only, since their decision to attend an ER or an OPD is determined by the intensity of their allergic reactions rather than by their insurance status. HCUP State Emergency Department Dataset (HCUP SEDD) for the state of Maryland (1999 – 2008) is exploited to track both insured and uninsured patients. Each year, it provides records for thousands of patients diagnosed with particular food allergy types (e.g. allergy to seafood, milk etc). The fact that SEDD does not capture ER visits, which result in hospitalization, does not significantly impact our analysis, since the rate of hospitalizations does not exceed 1.5 percent of all ER patients diagnosed with food allergies (HCUPnet , 2012). The state of Maryland is used for several reasons. First, it is one of the few states reporting ER data for as early as 1999. This allows me to cover several years in the pre-regulation period. Second, it provides the data at a cost justified for research purposes³. With both NHAMCS and SEDD, I use only those time periods when the sampling methodology did not change. This ensures that fluctuations in the number of food allergies result from the information campaigns rather than from variations in sampling methodology.

Table 3.1⁴ outlines a composition of food allergies and justifies our definition of the allergy

³This study would benefit from using the state of Maryland OPD data as well. This would allow me to incorporate information for the full set of allergy sensitivity types, including cases recorded at OPDs and ERs. However, this information is not part of HCUP project. The state sets its own pricing policy and charges about 2,500 per year (Form OPRESERACH (2012)).

⁴Tables 3.1-3.3 report the weighted number of NHAMCS visits and the actual number of HCUP SEDD visits. As for NHAMCS data, the actual number of visits with food allergies varies around 200 – 300 observations per time period, the number of non-allergy control diseases varies from two to five thousand cases, and the number of non-food allergies changes from one to three thousands per period.

Table 3.1: Composition of Food Allergies

	OPD (lower risk reference)			ER (higher risk reference)			SEDD (ER)		
	Pre- Intervention (1997-2000) (1)	Voluntary Disclosure (2001-2005) (2)	Mandatory Disclosure (2006-2007) (3)	Pre- Intervention (1997-2000) (4)	Voluntary Disclosure (2001-2005) (5)	Mandatory Disclosure (2006-2007) (6)	Pre- Intervention (1999-2000) (7)	Voluntary Disclosure (2001-2005) (8)	Mandatory Disclosure (2006-2008) (9)
Anaphylactic shock due to food reactions	0.001	0.000	0.006	0.078	0.018	0.089	0.090	0.070	0.050
Allergy to peanuts	0.000	0.000	0.005	0.000	0.022	0.000	0.010	0.060	0.110
Allergy to seafood	0.045	0.077	0.055	0.211	0.178	0.218	0.080	0.140	0.310
Allergy to eggs	0.000	0.000	0.010	0.000	0.000	0.000	0.000	0.020	0.050
Allergy to milk products	0.620	0.455	0.588	0.175	0.068	0.012	0.070	0.090	0.090
Allergic gastroenteritis due to food	0.000	0.055	0.213	0.000	0.011	0.089	0.010	0.020	0.010
Allergic rhinitis due to food	0.000	0.007	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Cutaneous reactions due to food (*)	0.000	0.003	0.000	0.000	0.015	0.000	0.020	0.010	0.000
Dermatitis due to food	0.334	0.372	0.187	0.536	0.690	0.509	0.720	0.470	0.170
Other adverse food allergic reactions	0.000	0.032	0.074	0.000	0.052	0.094	0.040	0.210	0.350
Number of Cases	54,909	78,590	33,455	47,119	93,851	35,980	3,102	6,692	36,852
Number of cases per 10,000 ER/OPD patients	5.92	14.23	12.49	5.04	2.47	3.02	8.61	12.93	32.67

(*) Cutaneous reactions include urticaria, flushing, angioedema, and other eczema due to food.

(i) Dubious cases have symptoms observed with both life-threatening and milder food allergies.

Source: NHAMCS outpatient department (OPD) and emergency room (ER) records for 1997-2007; HCUP SEDD emergency room records for 1999-2008.

sensitivity types. NHAMCS OPDs records of insured patients are largely dominated by milder food allergies, while ERs predominantly document life-threatening cases. In SEDD ER records of insured and uninsured patients, life-threatening allergies represent about 20 – 30 percent cases, and milder allergies - about 10 percent cases. This confirms our hypotheses that (i) insured patients attend an OPD or an ER based on the intensity of their allergies, while (ii) uninsured patients attend an ER with both life-threatening and milder food allergies.

The number of "Dubious" cases, having symptoms similar to both life-threatening and milder allergies, is high in both outpatient and emergency departments. When I compare NHAMCS OPD and ER files, I analyze all OPD/ER visits, including life-threatening, milder and "dubious" food allergies. When I look at SEDD ERs, I ignore "dubious" cases and compare life-threatening cases to milder food allergies.

Food Allergies and their Synthetic Controls

I evaluate the efficacy of the information campaigns by looking at the number of food allergy visits and compare the trends for the life-threatening and milder food allergies over time. Since the information campaigns are nationwide, I compare food allergies to a convex combination of non-allergy diseases ([Abadie et al., 2010, 2003](#)). This allows controlling for unobserved advancements in medical technology targeting particular disease symptoms. A synthetic control group is represented by a weighted average of non-allergy diagnoses, with weights chosen so that the resulting synthetic "food allergies" mimic the trajectory of food allergy visits prior to 2001, when the first allergen labeling regulation went into effect, and reproduce the values of a set of predictors of OPD/ER food allergies in the pre-intervention period. The set of predictors, summarized in Tables 3.1-3.2, includes patient socio-economic and insurance characteristics (NHAMCS and SEDD); hospital characteristics (NHAMCS), and visit characteristics (SEDD).

Table 3.2: Food Allergies and their Control Diseases by Selected Characteristics (NHAMCS)

	OPD (lower risk reference)			ER (higher risk reference)			Control Diseases (i)			Control Diseases (ii)		
	A (1)	B (2)	C (3)	A (4)	B (5)	C (6)	A (7)	B (8)	C (9)	A (10)	B (11)	C (12)
Patients' Socio-Economic Characteristics, frequencies												
Mean Patient's age, years	44.41 (10.07)	25.22 (4.519)	35.41 (9.816)	34.91 (4.528)	26.11 (1.979)	25.86 (4.359)	40.86 (0.502)	41.47 (0.567)	45.11 (0.875)	30.67 (0.718)	31.85 (0.787)	33.07 (1.312)
Patient Race: White	0.786	0.697	0.578	0.638	0.816	0.521	0.836	0.823	0.738	0.764	0.702	0.631
Patient Race: Black	0.128	0.274	0.13	0.226	0.138	0.456	0.141	0.145	0.175	0.203	0.259	0.272
Patient Race: Asian	0.086	0.029	0.052	0.063	0.044	0.002	0.019	0.019	0.012	0.027	0.022	0.016
Patient Sex: Female	0.651	0.451	0.566	0.624	0.62	0.504	0.541	0.572	0.547	0.579	0.59	0.608
Patients' Insurance Characteristics, frequencies												
Private	0.724	0.922	0.893	0.87	0.98	0.942	0.745	0.738	0.763	0.834	0.821	0.855
Medicare	0.276	0.078	0.352	0.13	0.019	0.058	0.255	0.276	0.347	0.166	0.184	0.189
ER/OPD Characteristics, frequencies												
MSA area	0.627	0.966	0.832	0.758	0.914	0.943	0.751	0.749	0.766	0.817	0.821	0.854
Location: Northeast	0.317	0.232	0.554	0.344	0.259	0.080	0.170	0.152	0.165	0.252	0.236	0.204
Location: Midwest	0.175	0.211	0.114	0.082	0.144	0.147	0.328	0.332	0.313	0.326	0.285	0.267
Location: South	0.470	0.362	0.276	0.401	0.286	0.518	0.365	0.366	0.386	0.258	0.326	0.330
Number of Cases, thousand patients	54.9	78.5	33.5	47.1	93.9	35.9	13,898	19,937	7,057	7,564	11,124	3,990
Number of cases per 10,000 ER/OPD patients	5.92	14.23	12.49	5.04	2.47	3.02	37.21	29.05	28.43	6.38	5.39	4.69

Columns: A - pre-regulation period (1997-2000); B - voluntary risk information disclosure (2001-2005); C - mandatory risk information disclosure (2006-2010). Source: NHAMCS outpatient department (OPD) and emergency room (ER) records for 1997-2007.

Since both voluntary and mandatory allergen disclosure affects the entire country, I compare food allergies to a synthetic control group represented by a weighted average of control diseases, with weights chosen so that the resulting synthetic "food allergies" best reproduce the values of a set of predictors of food allergy visits prior to 2001, when the first allergen labeling regulation went into effect. The set of predictors includes patient socio-economic characteristics including their race, gender, and age; patient insurance characteristics; and hospital characteristics including its location and MSA status. Synthetic Control Group (i) consists of non-allergy diagnoses, and it controls for unobserved advancements in medical technology targeting symptoms similar to food allergies. Synthetic Control Group (ii) consists of non-food allergies, and it controls for medical advancements in treating allergies.

Control Diseases (i) = $0.253 \times \text{Dermatitis} + 0.747 \times \text{Bronchitis}$; Control Diseases (ii) = $0.138 \times \text{Allergic Asthma} + 0.862 \times \text{Allergic Conjunctivitis}$.

Table 3.3: Food Allergies and their Control Diseases by Selected Characteristics (SEDD)

	Life-Threatening Cases			Milder Cases			Control Diseases (iii)		
	A (1)	B (2)	C (3)	A (4)	B (5)	C (6)	A (7)	B (8)	C (9)
Patients' Socio-Economic Characteristics, frequencies									
Mean Patient's age, years	28.16 (18.92)	26.56 (20.37)	28.50 (21.32)	18.90 (22.88)	18.63 (23.47)	18.94 (22.20)	27.66 (18.71)	27.82 (19.01)	26.86 (19.40)
Patient Sex: Female	0.51	0.52	0.55	0.51	0.49	0.53	0.56	0.57	0.57
Patient Race: White	0.50	0.42	0.40	0.45	0.48	0.46	0.34	0.35	0.36
Patient Race: Black	0.40	0.51	0.54	0.51	0.44	0.46	0.61	0.61	0.57
Patient Race: Asian	0.00	0.00	0.01	0.00	0.00	0.02	0.00	0.00	0.01
Patient Race: Other	0.09	0.07	0.05	0.04	0.07	0.06	0.05	0.04	0.05
Patients' Insurance Characteristics, frequencies									
Medicare	0.05	0.07	0.10	0.06	0.08	0.09	0.05	0.05	0.06
Medicaid	0.09	0.22	0.29	0.24	0.35	0.43	0.15	0.23	0.27
Private	0.73	0.58	0.50	0.60	0.52	0.43	0.61	0.58	0.53
Self-Pay	0.84	0.72	0.69	0.71	0.58	0.58	0.79	0.71	0.70
No Charge	0.00	0.01	0.01	0.00	0.00	0.00	0.00	0.00	0.00
Other	0.02	0.02	0.03	0.02	0.03	0.03	0.01	0.02	0.03
Visit Characteristics, means									
Length of stay, days	0.00 (0.00)	0.20 (0.42)	0.18 (0.40)	0.00 (0.00)	0.18 (0.39)	0.18 (0.39)	0.00 (0.00)	0.11 (0.32)	0.12 (0.34)
Number of diagnoses	2.55 (1.31)	3.49 (2.11)	4.53 (2.75)	2.31 (1.26)	3.77 (2.45)	4.79 (2.76)	2.20 (1.12)	2.69 (1.54)	3.02 (1.82)
Number of procedures	1.25 (1.66)	3.80 (3.49)	4.97 (4.19)	1.62 (2.13)	4.20 (3.81)	5.19 (4.59)	1.26 (1.54)	3.04 (2.71)	3.88 (3.87)
Total charges	224.84 (188.63)	408.02 (459.36)	525.66 (500.82)	263.02 (475.10)	436.27 (500.80)	542.10 (551.14)	202.99 (1157.62)	266.22 (323.45)	378.51 (453.54)
Number of Cases	528	1739	6626	237	799	2285	6134	12789	20922
Number of cases per 10,000 ER patients	1.11	3.27	11.86	0.69	1.35	3.63	13.29	21.61	28.63

Columns: A - pre-regulation period (1999-2000); B - voluntary risk information disclosure (2001-2005); C - mandatory risk information disclosure (2006-2008). Source: HCUP SEDD emergency room records for 1999-2008.

Since both voluntary and mandatory allergen disclosure affects the entire state, I compare food allergies to a synthetic control group represented by a weighted average of control diseases, with weights chosen so that the resulting synthetic "food allergies" best reproduce the values of a set of predictors of food allergy visits prior to 2001, when the first allergen labeling regulation went into effect. The set of predictors includes patient socio-economic characteristics including their race, gender, and age; patient insurance characteristics; and visit characteristics including length of stay, number of diagnoses and procedures, and total charges. Synthetic control group consists of non-food allergies, and it controls for medical advancements in treating allergies.

Control Diseases = $0.82 * \text{Allergic Rhinitis} + 0.124 * \text{Allergic Purpura} + 0.056 * \text{Allergic Pneumonitis}$.

The set of control group diseases (the "donor pool") consists of diseases that satisfy the following criteria. First, they have both chronic and acute phases, which match composition of food allergies. Second, they have symptoms observed in food allergies. This allows controlling for unobserved advancements in medical technology targeting patients with particular symptoms. Third, they are represented by non-allergy diagnoses. Since allergies are provoked by particular genes, patients who do not have these genes do not suffer from allergies (Nowak-Wegrzyn et al., 2001; Venter et al., 2006). Therefore, disclosure of allergen content in foods does not affect patients not having those genes even though symptoms of their disease are similar to allergies⁵. Among all donor pool diseases, I choose those with minimum pseudo distance between the synthetic control unit and food allergies, and those with the trajectory of the outcome variable similar to food allergies in the pre-treatment period (Abadie et al., 2010, 2003).

As a robustness check, I compare food allergies to a different synthetic control represented by non-food allergies. This group aims at controlling for medical advancements that relieve allergy symptoms (e.g. sales of allergy-related medications or their availability over-the-counter). Including those variables directly into the model is rather problematic. First, the list of allergy-related medications consists of a wide range of options including pills, liquids, inhalers, nasal sprays, eye drops, skin creams and injections (Boyce et al., 2010; Bischoff, 2007). Some of them (e.g. epinephrine, mast cell stabilizers, immunomodulators, some antihistamines and corticosteroids) target more intensive or life threatening allergic reactions and therefore require a prescription. Dozens of others (e.g. decongestant sprays, eye drops, skin creams etc.) address less intensive allergies and are available over-the-counter. Second, availability of these medications over-the-counter changes over time. For instance, Claritin, having the highest market share among allergy-related medications (37.5 percent sales), became available OTC in December, 2002. However, by that time the first-generation

⁵The full list of food and non-food allergies as well as non-allergy diagnoses is provided in Appendix 3.B.

antihistamines such as Benadryl were already available OTC. Finally, availability of these medications over-the-counter favors predominantly consumers without health insurance, while insured patients might switch to prescription drugs (e.g. Allegra or Zyrtec) if they are covered by their insurance (Petersen, 2002). An alternative synthetic control specification allows both treatment and control group to be equally affected by the medical advancements in anti-allergen medications. In this way, I indirectly control for fluctuations in allergy visits driven by technological improvements in allergy medications or their availability on the market.

While constructing the alternative control group that consists of non-food allergies, I excluded from the "donor pool" all allergies having symptoms frequently observed in food allergies and use only those with symptoms rare in food allergies⁶. In this way I exclude a wide range of allergies that might be misdiagnosed with food allergies (Niggemann et al., 2007; Roberts, 2005). The remaining "donor pool" consists of non-food allergies that might only be triggered by the food allergies (Nowak-Wegrzyn et al., 2001; Venter et al., 2006). Since the remaining non-food allergies might still be indirectly affected by food allergies, comparing food allergies to the second synthetic control group - allergies with symptoms rare in food allergies- provides the lower bound of the effect of the allergen labeling regulation.

Estimation and Results

Patients with Different Susceptibility to Allergens: NHAMCS Sample

I estimate the difference in consumer reaction to allergen warnings by looking at the number of visits with higher and lower allergen susceptibility per 10,000 OPD/ER visits, registered during a month t at an OPD/ER h located at the strata s . I use a negative binomial model with

⁶The composition of food allergies is reported in Table 3.1, and the full list of allergies including those with symptoms similar to food allergies and those with symptoms different from food allergies is provided in Appendix 3.B.

quadratic variance and exploit a difference-in-differences framework. The first difference contrasts patients with higher and lower susceptibility to food allergens, and the second difference compares the number of visits in the pre- and post-regulation period:

$$f(A_{hst}) = \alpha_0 + \alpha_1 * HRS_{hst} \times Regulation_t + \alpha_2 \times Regulation_t + \alpha_3 \times HRS_{hst} + \alpha_4 * C_{hst} + \alpha_5 \times X_{hst} + \alpha_6 \times H_{hst} + \alpha_7 \times \delta_h + \alpha_8 \times \tau_t + e_{sth} \quad (3.1)$$

where A_{hst} represent the number of patients with food allergies, C_{hst} measures the number of patients with control group diseases, HRS_{hst} is a dummy variable that takes the value of one if a visit is recorded at an emergency room and zero - in an OPD, X_{hst} is a set of socio-economic and health insurance characteristics of patients averaged at a hospital level, H_{hst} is a set of OPD/ER characteristics, δ_h are strata fixed effects, and τ_t represents year polynomial time trend and month fixed effects (Table 3.2 and Appendix 3.1). Polynomial time trend is a flexible tool to capture the information specific to a particular year given that $Regulation_t$ dummies are multicollinear with the year fix effects. Months fixed effects account for the seasonality of allergies. $Regulation_t$ is represented by two different dummy variables. A voluntary regulation dummy takes the value of one for all time periods after April 2001 when NFPA guidelines advised manufacturers to label allergen content voluntary, and a mandatory regulation dummy equals one for all time periods after January 2006 when the Federal mandate went into effect. $HRS_{hst} \times Regulation_t$ is our variable of interest. It demonstrates if the impact of the allergen content disclosure on patients with higher reference risk is statistically different from its impact on the lower reference risk group. To account for endogenously varying probability to sample certain PSUs, OPDs/ERs within PSUs, and patient visits within clinics and emergency service areas, I use survey weights in all results presented (CDC, 2012; Solon, Haider and Wooldridge, 2013).

Figure 3.1 outlines the trend in food allergies with higher and lower reference risk, and

Table 3.4: **Impact of the Legislation on Food Allergies over Time (NHAMCS)**, incidence ratios

	Control Diseases (i)				Control Diseases (ii)			
	Through 2002 (1)	Through 2003 (2)	Through 2005 (3)	Through 2007 (4)	Through 2002 (5)	Through 2003 (6)	Through 2005 (7)	Through 2007 (8)
High Reference Risk, Voluntary Disclosure	0.482** (0.169)	0.552* (0.188)			0.497* (0.182)	0.549* (0.188)		
Voluntary Disclosure	2.325** (0.779)	1.914** (0.576)			2.277** (0.789)	1.890** (0.597)		
High Reference Risk, Mandatory Disclosure			1.192 (0.510)	0.866 (0.283)			1.141 (0.481)	0.999 (0.341)
Mandatory Disclosure			1.875* (0.690)	1.872** (0.526)			1.935* (0.705)	1.814** (0.515)
High Reference Risk	1.364 (0.412)	1.239 (0.352)	0.767 (0.152)	0.914 (0.174)	1.353 (0.422)	1.265 (0.368)	0.792 (0.155)	0.907 (0.168)
Control Diseases	1.007* (0.004)	1.006 (0.004)	1.004 (0.004)	1.003 (0.004)	1.015 (0.011)	1.022* (0.012)	1.010 (0.010)	1.015 (0.012)
Number of ERs/OPDs	6,613	7,728	9,666	11,716	6,613	7,728	9,666	10,747

Note 1: Since both voluntary and mandatory allergen disclosure affects the entire country, I compare food allergies to a synthetic control group represented by a weighted average of control diseases, with weights chosen so that the resulting synthetic "food allergies" best reproduce the values of a set of predictors of food allergy visits prior to 2001, when the first allergen labeling regulation went into effect. The set of predictors includes patient socio-economic characteristics including their race, gender, and age; patient insurance characteristics; and hospital characteristics including its location and MSA status. Synthetic Control Group (i) consists of non-allergy diagnoses, and it controls for unobserved advancements in medical technology targeting symptoms similar to food allergies. Synthetic Control Group (ii) consists of non-food allergies, and it controls for medical advancements in treating allergies.

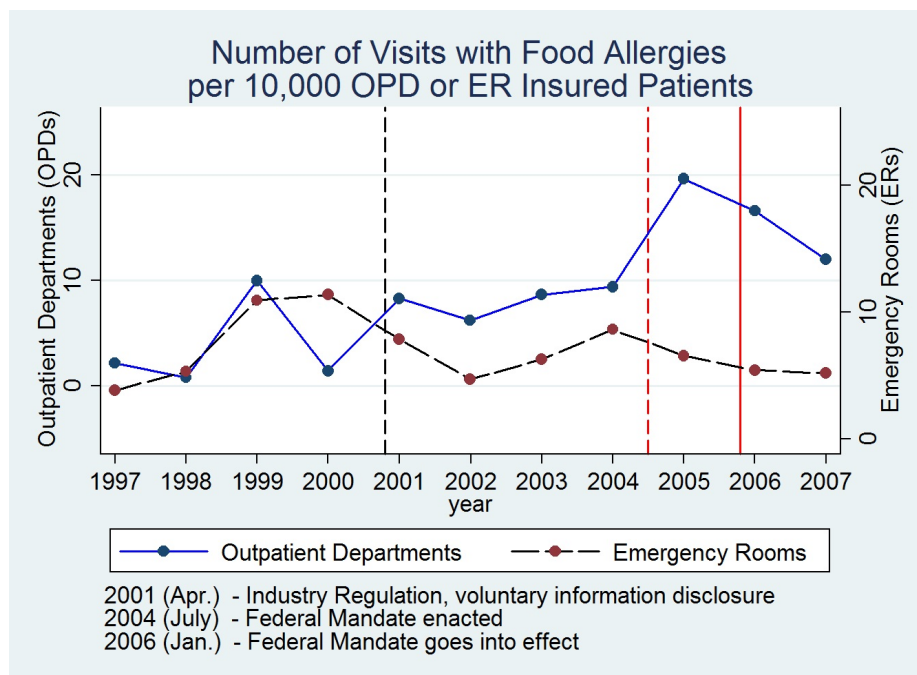
Control Diseases (i) = $0.253 \times \text{Dermatitis} + 0.747 \times \text{Bronchitis}$;

Control Diseases (ii) = $0.138 \times \text{Allergic Asthma} + 0.862 \times \text{Allergic Conjunctivitis}$.

Note 2: In all regressions, while not reported, I also include the following controls: (i) patients' socio-economic characteristics including their age, race, and gender, (ii) patients insurance characteristics, (iii) hospital characteristics including its location and MSA status, (iv) strata fixed effects, polynomial year time trend, months fixed effects (definitions of the variables are provided in Appendix 1). Stars denote significance levels: 99 percent confidence level (***), 95 percent confidence level (**), and 90 percent confidence level (*).

Data Source: NHAMCS outpatient department (OPD) and emergency room (ER) records for 1997-2007.

Figure 3.1: Food Allergies with Higher and Lower Sensitivity to Risk (NHAMCS)



Source: NHAMCS outpatient department (OPD) and emergency room (ER) records for 1997-2007.

Note: OPD sample represents consumers with lower susceptibility to risk; ER sample reflects patients with higher risk sensitivity.

Table 3.3 summarizes the primary results of this specification. Columns 1-4 of the table compare food allergies to non-allergy diagnoses, and columns 5-8 compare food to non-food allergies. Table 3.3 demonstrates that the estimated effect of the information campaigns on allergic consumers with different susceptibility to food allergens is robust to the choice of a synthetic control group.

Our analysis highlights several important findings. First, food allergen warnings impact predominantly patients with the lower sensitivity to allergens. Initially, the number of these patients was extremely volatile. After NFPA introduced its industry guidelines in April 2001, the number of these patients stabilized at a level that exceeds the pre-NFPA period average by about 89 – 91 percent. An enactment of the Federal mandated is associated with a 87 – 93 percent 1.5-year increase in food allergies, followed by their slight decline after the mandate went into effect in January 2006. On the contrary, the number of patients with the higher susceptibility to food allergens was almost unaffected by both information campaigns. The trend for higher reference risk food

allergies is relatively flat, and their incidence ratios in different years do not differ much from the unity, implying a zero percent change in the corresponding variable.

Second, our results allow comparing consumers' response to a voluntary and mandatory disclosure of allergen warnings. Voluntary disclosure did not significantly change the number of vulnerable patients regardless of their risk sensitivity types, while the mandate resulted in substantial fluctuations in the number of patients with the lower allergen susceptibility. This result provides some evidence that unified disclosure standard, introduced by the mandate, might be preferred to non-standardized voluntary improvements in the warning clarity.

Patients with Different Susceptibility to Allergens: SEDD Sample

HCUP SEDD data for the state of Maryland allows comparing patients with higher and lower susceptibility to the risk based on symptoms of their food allergies. However, in this setting a direct difference-in-differences procedure cannot be incorporated, since the same SEDD emergency room may admit both patients with higher and with lower sensitivity to food allergens. I address this problem in two different ways. First, I estimate separately the impact of the risk information campaigns on consumers having higher and lower allergen susceptibility:

$$f(A_{hst}) = \alpha_0 + \alpha_1 * Regulation_t + \alpha_2 * C_{hst} + \alpha_3 * X_{hst} + \alpha_4 * V_{hst} + \alpha_5 * \delta_h + \alpha_6 * \tau_t + u_{sth} \quad (3.2)$$

where A_{hst} represent the number of visits with higher or lower susceptibility to food allergens per 10,000 ER visits, V_{hst} stands for visit characteristics, including length of stay, total number of ICD-9 diagnoses and CPT/HCPCS procedures, δ_h represents county fixed effects, and the rest of the specification is defined as before (Table 3.3 and Appendix 3.1). Since county-specific fixed effects do not completely control for within-county error correlation, I use cluster-robust standard errors.

Taking into account a limited number of ERs within a county, I utilize heteroskedasticity-robust rather than county-clustered error correction methodology⁷ (Cameron and Miller, 2011).

Second, I compare patients with the lower reference risk to those having higher reference risk by introducing a two-step procedure. The first step estimates the number of allergies with the *higher* reference risk controlling for the number of control group diseases. The second step focuses on allergies with *milder* reference risk controlling for the reference group diseases and higher reference risk visits estimated from the first step (Cameron and Trivedi, 2013; Imai, 2011):

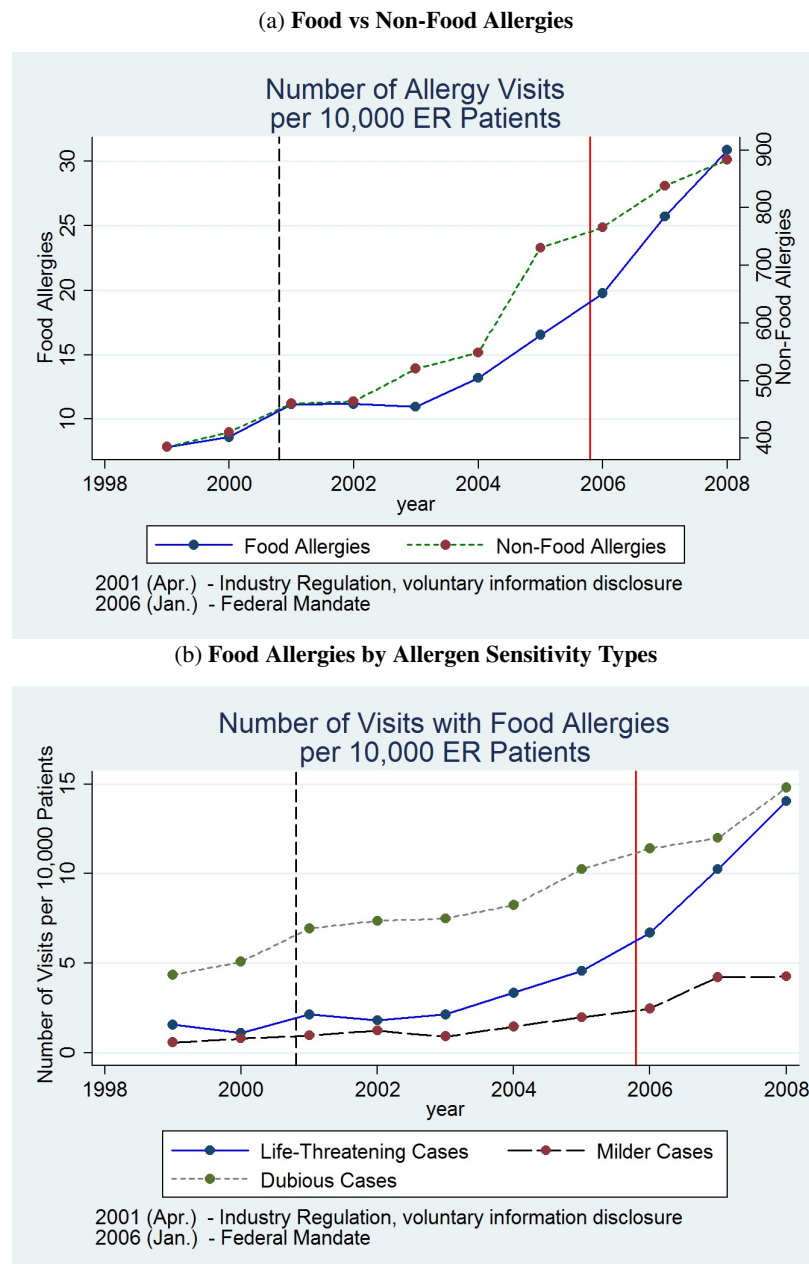
$$f(M_{hst}) = \alpha_0 + \alpha_1 * Regulation_{1t} + \alpha_2 * T_{hst} + \alpha_3 * C_{hst} + \alpha_4 * X_{hst} + \alpha_5 * V_{hst} \\ + \alpha_6 * \delta_h + \alpha_7 * \tau_t + v_{sth} \quad (3.3)$$

$$f(T_{hst}) = \beta_0 + \beta_1 * Regulation_{2t} + \beta_2 * C_{hst} + \beta_3 * X_{hst} + \beta_4 * V_{hst} \\ + \beta_5 * \delta_h + \beta_6 * \tau_t + \epsilon_{sth} \quad (3.4)$$

where M_{hst} represents the number of visits with milder allergic reactions per 10,000 ER visits, and T_{hst} stands for visits with life-threatening food allergies per 10,000 ER visits. In this setting, T_{hst} in the first equation is regarded as an endogenous variable correlated with v_{sth} . This assumption may be rationalized in terms of omitted unobserved characteristics of an ER if it admits patients with milder food allergies and patients with life-threatening allergic reactions. A sequential two-step procedure estimates the first of the equations after replacing T_{hst} by an estimate of $E[T_{hst} | Regulation_{2t}, C_{2hst}, X_{2hst}, V_{2hst}, \delta_{2h}, \tau_{2t}]$, which is uncorrelated with v_{sth} . This amounts to an instrumental variable procedure (Cameron and Trivedi, 2013), where the set of excluded exogenous variables consists of higher powers of continuous variables including patients' age and lengths of stay, and higher powers of the time trend (Escanciano, Jacho-Chávez and Lewbel, 2010).

⁷The same error correction methodology is applied to all SEDD specifications.

Figure 3.2: Number of Patients with Allergies over Time (SEDD)



Source: HCUP SEDD emergency room records for 1999-2008.

Note:

- Life-threatening cases (higher susceptibility to allergens) consist of anaphylactic shock due to food reactions, allergy to peanuts, and allergy to seafood;
- Milder cases (lower susceptibility to allergens) consist of allergy to eggs, milk products, and gastroenteritis due to food;
- Dubious cases (excluded from our analysis) have symptoms observed with both life-threatening and milder food allergies, and consist of allergic rhinitis and dermatitis due to food, cutaneous reactions, and other adverse food reactions.

Table 3.5: Impact of the Legislation on Food Allergies by Allergen Sensitivity Types (SEDD), incidence ratios

	All Patients			Insured Patients*			Uninsured Patients		
	Life-Threat. Allergies (1)	Milder Allergies (2)	Milder, 2nd step (3)	Life-Threat. Allergies (4)	Milder Allergies (5)	Milder 2nd step (6)	Life-Threat. Allergies (7)	Milder Allergies (8)	Milder 2nd step (9)
Voluntary Disclosure	0.925 (0.141)	1.082 (0.160)	1.144 (0.149)	0.912 (0.672)	0.210 (0.261)	0.402 (0.445)	1.291 (0.457)	0.822 (0.275)	0.802 (0.246)
Mandatory Disclosure	1.983*** (0.177)	1.452*** (0.132)	0.759 (0.137)	1.023 (0.518)	0.237** (0.169)	0.214** (0.157)	1.729*** (0.329)	1.189 (0.262)	0.828* (0.352)
Number of ERs	1,778	1,778	1,778	1,714	1,714	1,714	1,726	1,726	1,726

Note 1: (*) This specification is directly comparable to results based on NHAMCS sample, which represents insured patients only.

Note 2: Since both voluntary and mandatory allergen disclosure affects the entire country, I compare food allergies to a synthetic control group represented by a weighted average of control diseases, with weights chosen so that the resulting synthetic "food allergies" best reproduce the values of a set of predictors of food allergy visits prior to 2001, when the first allergen labeling regulation went into effect. The set of predictors includes patient socio-economic characteristics including their race, gender, and age; patient insurance characteristics; and visit characteristics including length of stay, number of diagnoses for a visit, number of procedures for a visit, and total charges. Synthetic Control Group consists of non-food allergies, and it controls for medical advancements in treating allergies.
 $\text{Synthetic Control} = 0.82 * \text{Allergic Rhinitis} + 0.124 * \text{Allergic Purpura} + 0.056 * \text{Allergic Pneumonitis}$.

Note 3: In all regressions, while not reported, I also include the following controls: (i) patients' socio-economic characteristics including their age, race, and gender, (ii) patients insurance characteristics, (iii) visit characteristics including length of stay, number of diagnoses for a visit, number of procedures for a visit, and total charges, (iv) county fixed effects, polynomial year time trend, months fixed effects (definitions of the variables are provided in Appendix A). The first two columns of every specification (e.g. columns 4-5) report the independent estimates of the impact of information campaigns on the life-threatening and milder allergies respectively. The 3rd column of every specification (e.g. column 6) evaluates the impact of information campaigns on milder allergies, controlling for the number of life-threatening allergies estimated in the 1st column. Stars denote significance levels: 99 percent confidence level (***), 95 percent confidence level (**), and 90 percent confidence level (*). Data Source: HCUP SEDD emergency department records for 1999-2008.

Figure 3.2 outlines the trend for SEDD food allergies of different sensitivity types, and it demonstrates that the numbers of food allergies is constantly increasing over the course of 1999 – 2008. In this setting, a risk information campaign can be considered efficient if it reduces the rate of growth in food allergies compared to non-food allergies. According to Figure 3.2, an overall increase in food allergies is analogous to non-food cases. Life-threatening allergies (higher reference risk group) also increase at the same rate as non-food allergies. However, milder allergies (lower reference risk) increase three times slower compared to non-food allergies, and this effect is the most pronounced after the Federal mandate got enacted in 2004.

Table 3.5 bolsters graphics analysis and reports the estimation results for the full sample of allergic patients first, and then breaks it down by patients' insurance status. Columns 1-2, 4-5, and 7-8 correspond to a specification, represented by equation (3.2). Columns 3, 6, and 9 outline results for a second step of two-step procedure described in equation (3.4), given that the first step is reported in columns 1, 4, and 7 respectively. Table 3.5 presents suggesting evidence that the primary conclusions of this paper hold regardless of the choice of the datasets or specifications. First, similarly to results based on NHAMCS, voluntary disclosure of the allergen content in food did not affect consumers regardless of their risk susceptibility type: all the corresponding incidence ratios are statistically insignificant, and they do not differ from a unity, which implies a zero percent change in a corresponding variable. Second, consumers with the milder sensitivity to allergens benefit more from the risk information campaigns. Regardless of patient insurance type, the number of life-threatening allergies remained either unchanged or continued to increase. At the same time, the number of milder allergies in the post-mandate declined by 18 – 80 percent depending on patient's insurance status, and these coefficients are significant at 5 – 13 percent.

Taken together, the results in Table 3.5 substantiate our primary conclusion that risk information disclosure influences predominantly consumers with the lower reference risk. The higher

reference risk group is affected to a lesser extent, regardless of the definition of allergen susceptibility, patients insurance status, or the choice of control group diseases.

Patients with Different Prior Information about Their Allergies

Perhaps surprisingly, previous sections of this study provide conclusive and robust evidence that food allergen labeling campaigns affect consumers with the lower rather than higher allergen susceptibility. According to the literature, this may signify that public with the higher allergen sensitivity has better prior information about a set of potentially harmful ingredients. Consequently, they are less sensitive to an incremental change in their prior, attributable to voluntary or mandatory disclosure of the allergen content in foods.

Food allergy setup provides us with a unique opportunity to empirically test this hypothesis. In a case of food allergies, patients with higher sensitivity to allergens receive from medical practitioners the comprehensive information about their disease. First, they are informed of foods that most likely contain allergens, triggering their disease directly. Second, they are notified of other food allergens that cross-react with the allergens they are sensitive to (Appendix 3.C). Finally, they are advised to strictly avoid all the allergens affecting them directly or indirectly. On the contrary, consumers with the lower reference risk are notified predominantly of the "direct influence" allergens. Additionally, doctors do not see the need in dietary restrictions for this category of patients (Sicherer, 2011; Bischoff, 2007; Kurowski and Boxer, 2008). Since better prior information, received by patients with higher allergen sensitivity, is determined by the desire of medical practitioners to share this information rather than by the willingness of patients to learn more about their disease, the difference in consumers' prior is determined exogenously.

An exogenous variation in consumers' prior creates a unique opportunity to explore the link between consumers' prior information and their ability to avoid unhealthy products. Since better

prior information is provided by the medical practitioners, the *insured* patients have better access to this information before their current visit. On the contrary, *uninsured* patients have limited opportunities to discuss their allergies with a doctor, which results in less adequate prior. I cannot directly evaluate improvements in consumers prior, since different medical standards for notifying patients with different allergy sensitivity exist for quite a while. However, I can evaluate if consumers' response to the risk information campaigns depends on their prior. I do so by contrasting the impact of food allergen labeling on the insured and uninsured population of with the higher and lower susceptibility to allergens, and I exploit HCUP SEDD emergency department records that contain patients of both insurance types (Figure 3.3 and Table 3.6).

Table 3.6: **Impact of the Legislation on Food Allergies Controlling for Consumers' Prior (SEDD), incidence ratios**

	Life-Threatening Food Allergies			Milder Food Allergies		
	Uninsured Patients (1)	Insured Patients (2)	Insured, 2nd step (3)	Uninsured Patients (4)	Insured Patients (5)	Insured, 2nd step (6)
Voluntary Disclosure	1.291 (0.457)	0.912 (0.672)	0.785 (0.502)	0.822 (0.275)	0.210 (0.261)	0.324 (0.348)
Mandatory Disclosure	1.729*** (0.329)	1.023 (0.518)	0.301** (0.128)	1.189 (0.262)	0.237** (0.169)	0.206** (0.149)
Number of ERs	1,726	1,714	1,714	1,726	1,714	1,714

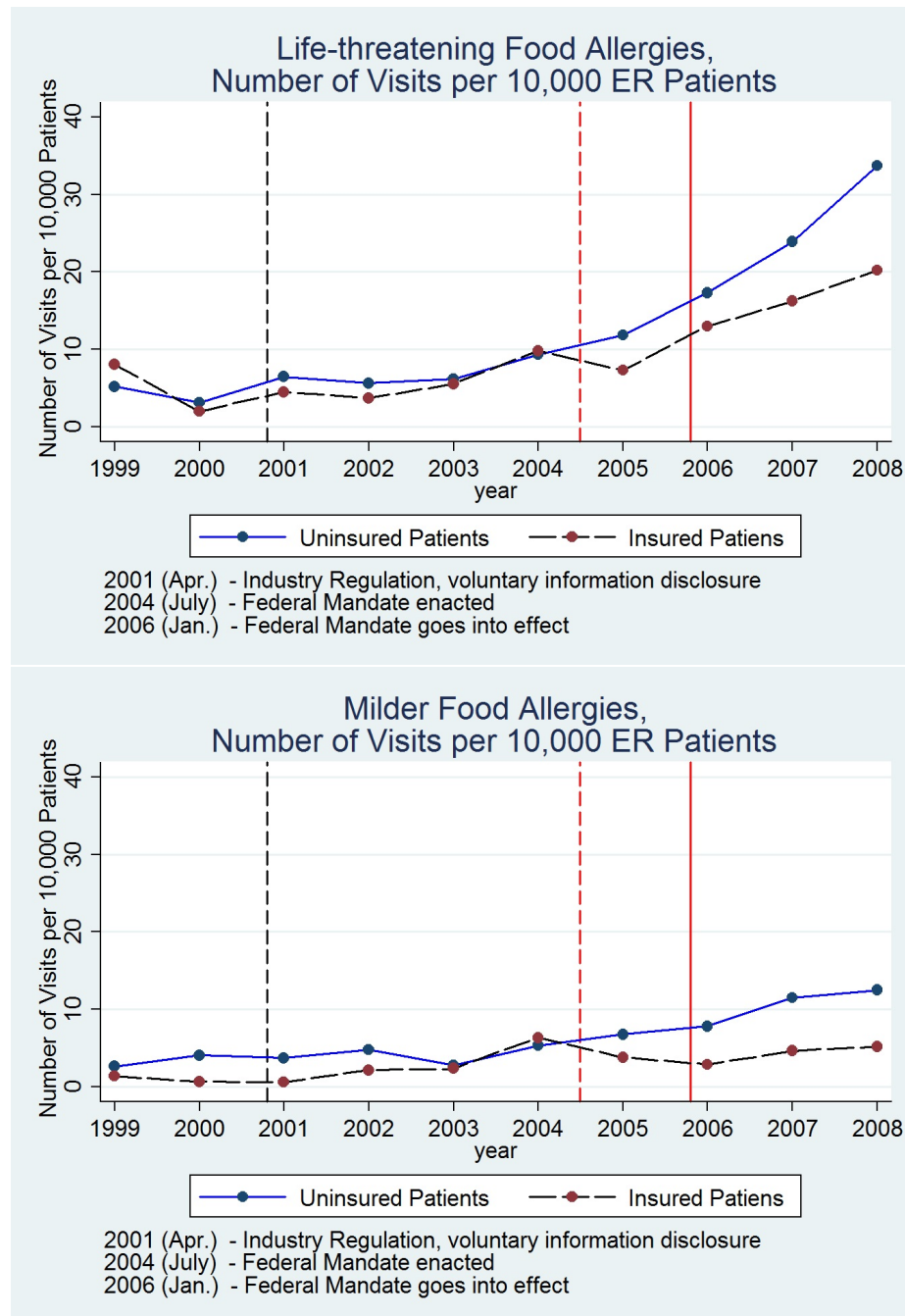
Note 1: See Figure 3.3 notes.

Note 2: See Table 3.5 notes. Synthetic Control=0.82*Allergic Rhinitis+0.124*Allergic Purpura+0.056*Allergic Pneumonitis.

Note 3: In all regressions, while not reported, I also include the following controls: (i) patients' socio-economic characteristics including their age, race, and gender, (ii) patients insurance characteristics, (iii) visit characteristics including length of stay, number of diagnoses for a visit, number of procedures for a visit, and total charges, (iv) county fixed effects, polynomial year time trend, months fixed effects (definitions of the variables are provided in Appendix A). The first two columns of every specification (e.g. columns 4-5) report the independent estimates of the impact of information campaigns on uninsured and insured patients respectively. The 3rd column of every specification (e.g. column 6) evaluates the impact of information campaigns on insured patients, controlling for the number of uninsured patients estimated in the 1st column. Stars denote significance levels: 99 percent confidence level (***), 95 percent confidence level (**), and 90 percent confidence level (*). Data Source: HCUP SEDD emergency department records for 1999-2008.

Since the same SEDD emergency room may admit both insured and uninsured patients, I exploit a two-step procedure outlined by equations (3.3)-(3.4). In this case, the first step estimates

Figure 3.3: Food Allergies by the Allergen Sensitivity Types: Insured vs Uninsured Patients (SEDD)



Note 1: These graphs compare insured patients to uninsured population by the risk sensitivity types. Insured patients benefit from comprehensive information about their food allergies, provided by the medical practitioners. Therefore, these patients are equipped with better prior information about their disease compared to uninsured patients. Since the excess to the comprehensive information is determined by the insurance status rather than by the desire of higher reference risk patients to learn more about their disease, the difference in consumers' prior is determined exogenously.

Note 2: Life-threatening cases (higher susceptibility to allergens) consist of anaphylactic shock due to food reactions, allergy to peanuts, and allergy to seafood. Milder cases (lower susceptibility to allergens) consist of allergy to eggs, milk products, and gastroenteritis due food.

the number of *uninsured* patients visiting an ER with their food allergies, and the second step focuses on *insured* patients controlling for uninsured patients estimated from the first step. The rest of the specification is defined as before.

Table 3.6 summarizes the major outcomes of this specification. Columns 1-3 report the estimated impact of allergen warnings on patients with life-threatening allergies, and columns 4-6 outlines the impact on patients with the milder food allergies. Columns 3 and 6 report estimates from the second step of a two-step procedure, which is the primary interest of this analysis. These columns outline the gains in consumers' perception that originates from a better excess to allergy-related information. Comparing the corresponding estimates from columns 3 and 6 allows me to explore if the excess to better allergy-related information translates into a different response to allergy warnings if consumers have different susceptibility to the allergens. Overall, columns 3 and 6 of Table 3.6 indicate that insured patients, who have better information about their disease, benefit substantially from the food allergen labeling campaigns compared to the uninsured population. The number of insured life-threatening food allergies in the post-mandate period decline by about 70 percent compared to uninsured patients. Similarly, the number of insured milder allergies decline by 79 percent compared to the uninsured population. A minor difference in the impact of a policy on life-threatening and milder cases (70 vs 79 percent respectively) allow me to conclude that consumers react to health warnings similarly, regardless of their sensitivity to the risk, if they have the same prior information about their disease. From a policy perspective, this result provides no evidence that intensity and visibility of a warning message needs to increase if an information campaign targets consumers with higher risk sensitivity.

Policy Implications: Mass vs Personalized Risk Information Campaigns

Previous section of this paper demonstrates that consumers do react to the health warnings regardless of their risk sensitivity type. Additionally, the framework of this study allows me to compare efficacy of the mass and personalized information campaigns (Table 3.5). Uninsured patients (columns 7-9) represent consumers with the least adequate prior information about their disease. Thus, the mass information campaigns, including voluntary and mandatory disclosure of the allergen content on food labels, would be the major source of their awareness of potentially harmful ingredients. On the contrary, insured patients (columns 4-6) have had an opportunity to discuss their food allergies with medical practitioners prior to their current ER visit. Therefore, for these patients the mass information campaigns are associated with the *marginal* improvements in their awareness of the health risks, compared to the personalized warnings, previously obtained from the medical practitioners.

Table 3.5 demonstrates that only those patients, who have received personalized allergy warnings, do benefit from the mass information campaigns. The number of *uninsured* patients, representing a clear-cut effect of a mass campaign, does not decline neither after voluntary nor after mandatory disclosure of the allergen content in foods. For instance, the number of milder allergies does not significantly change over time, as it can be seen from statistically insignificant incidence ratios that do not differ from the unity (column 8). The number of life-threatening cases rise at an increasing rate, regardless of the mass risk information campaigns (column 7). The estimated effect on *insured* patients, who might have obtained personalized health warnings, is dramatically different. The number of life-threatening visits changes no faster than the number of control diseases (column 4). The number of milder allergies drop by about 77 percent compared to control diseases only (column 5), and it decline by 79 percent compared to both control diseases and life-threatening

food allergies (columns 5 and 6 respectively).

This result demonstrates that personalized risk warnings are extremely important for vulnerable consumers. There is no evidence that allergic patients can avoid unsafe products if they have no access to individualized information. This calls for shifting regulatory effort from the mass campaigns towards patient-specific health risks notifications. In a special case of food allergies, the number of future visits with food allergies may decline if ER staff provides uninsured patients with the comprehensive allergen information, available to the insured public.

Conclusions

This paper focuses on risk information campaigns notifying the public about health risks associated with products and analyzes if consumer's response to the warnings depends on their sensitivity to the risk. As a policy example, we focus at food allergen labeling campaigns stressing the need to label ingredients responsible for the majority of food allergies. Vulnerable patients experience an allergic reaction just in a couple of hours after their contact with an allergen. Therefore, unlike many other diseases, food allergies allow to evaluate the immediate effect of health warnings. The methodological novelty of this study is to compare the public with higher and lower risk sensitivity. In this setting, both groups of customers observe the same warnings, disclosed at the same time, having the same clarity, related to the same goods having a given price, and pertaining to the same market. Therefore, different reaction to a negative signal results predominantly from *consumers' risk sensitivity* rather than from manufacturer willingness to disclose quality, market structure, or legislative environment.

The central finding of this paper is that risk disclosure affects predominantly consumers with *lower* sensitivity to the risk, while consumers with higher reference risk hardly respond to the warnings. This result is perhaps surprising, since patients with higher sensitivity are less willing

to bare the risk. However, they may have better prior information about their disease and, consequently, they might be less sensitive to the incremental improvements in their prior, attributed to the risk information campaigns.

I empirically test the hypothesis about consumer's prior by comparing insured and uninsured ER patients with different allergen sensitivity types. Insured patients have an opportunity to communicate to a doctor before their current ER visit and, thus, to update their prior information about the disease. On the contrary, an uninsured group has a limited access to medical advises, which results in less adequate prior. An important finding is that, controlling for patients' prior expectations about product safety, consumers react to the warnings similarly regardless of their risk susceptibility. From a policy perspective, this study fails to provide evidence that overwhelmingly intensive warnings are more likely to reach the public with the high reference risk. Instead, intensity of the warning has to be set at a level sufficient to the lower reference risk customers.

Additionally, this study contrasts consumer reaction to the mass risk information campaigns, initiated by industry or regulatory agencies, and to *personalized* risk warnings, effective in a pre-mass campaign era. A clear-cut opportunity to evaluate mass campaigns is to analyze their impact on uninsured patients. Uninsured public has the least adequate prior. Thus, mass campaigns are the major source of their awareness of harmful ingredients. On the contrary, for insured patients the mass campaigns are associated with the *marginal* improvements in their awareness of product safety. This paper finds no evidence that the mass campaigns provide the public with sufficient information to avoid hazardous products if consumers had no prior access to individualized risk warnings. This calls for shifting regulatory effort towards patient-specific health risks notifications.

Future extensions of this project will explore how consumers test and update their prior expectations about safety messages in response to health risks disclosure. Facing new allergen warnings, the vulnerable patients may choose to attend an OPD medical practitioner to update their prior.

However, if they believe their prior about safety messages is correct, they may "test" their prior and buy a product based on the observed warnings. If their expectations are erroneous, consumers visit an ER or an OPD with acute allergies. Since OPD admit both types of consumers, including those updating and testing their prior, I will zoom in on OPD sample, and compare the trends in the acute and non-acute food allergy visits before and after disclosure of the allergen content on food labels.

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Appendix 3.A: Definition of the variables

OUTCOME VARIABLES:

Number of Visits (NHAMCS and SEDD) - Number of patients with food allergies or control group diseases per 10,000 OPD/ER patients. A visit is defined as food allergies or control group disease if any of the three physician's diagnoses contain corresponding ICD-9 disease codes.

Urgency of Visits (NHAMCS OPD files) (Based on the "major reason for patient's visit" (MRV) variable. Since MRV contains only one reason for the current visit, the classification of allergy intensity types does not overlap)

- *Acute case* - Dummy variable that takes the value of one if MRV is indicated as a "visit for a condition, illness, or injury having a relatively sudden or recent onset (within three months of this visit)" or "a visit primarily due to sudden exacerbation of a pre-existing chronic condition".
- *Non-acute cases* - Dummy variable equals to one if MRCV is indicated as one of the following options: (i) "chronic routine problem (a visit primarily to receive care or examination for a pre-existing chronic condition, illness, or injury (onset of condition was three months or more before this visit)", (ii) "pre- or post- surgery (e.g., pre-surgery tests, removing sutures)", or (iii) "preventive care general medical examinations and routine periodic examinations (including annual physicals, screening, and insurance)".

CONTROL VARIABLES:

Food allergen labeling regulatory initiatives (NHAMCS and SEDD) including

- *Voluntary Disclosure* - Dummy variable indicating the period after the Industry guidelines went into effect (April 2001).
- *Federal mandate* - Dummy variable that equals one for all time periods after January 2006 when the Federal mandate went into effect.

Patients' Socio-Economic Characteristics (NHAMCS and SEDD)

Mean Patient's age, years - Mean patients' age in years.

Patient Race; includes dummies for White, Black, Asians, and patients of other races - Average number of patients of a certain race in an OPD/ER.

Patient Sex: Female - Average number of female patients in an OPD/ER.

Patients' Insurance Characteristics (NHAMCS and SEDD) (Based on PAYTYPE variable (NHAMCS)

or PAY1/PAY2 variables (SEDD) reporting primary expected source of payment for the current visit)

Private - Dummy variable equals to one if PAYTYPE =1 (NHAMCS) or PAY1/PAY2=3 (SEDD); includes Blue Cross, commercial carriers, and private HMOs and PPOs.

Medicare and Medicaid - Dummy variable equals to one if PAYTYPE=2 or PAYTYPE=3 respectively (NHAMCS), or PAY1/PAY2=1 or PAY1/PAY2=2 respectively (SEDD); includes both fee-for-service and managed care Medicare/ Medicaid/SCHIP patients.

Worker's Compensation - Dummy variable equals to one if PAYTYPE =4 (NHAMCS).

Self-Pay, No Charge, Other - Dummy variable equals to one if PAYTYPE =5, PAYTYPE =6, or PAYTYPE =7 respectively (NHAMCS) or PAY1/PAY2=4, PAY1/PAY2=5, PAY1/PAY2=6 respectively (SEDD).

OPD Characteristics (NHAMCS)

MSA area - Dummy variable indicating if a visit occurred in MSA location.

Location; includes dummies of Northeast, Midwest, and South - Dummy variable indicating if an OPD is located in a certain Census region.

Visit Characteristics (SEDD)

Length of stay, days - Average length of stay in an ER for a visit, days.

Number of diagnoses - Average number of ICD-9 diagnoses for a visit.

Number of procedures - Average number of CPT/HCPCS procedures on a record.

Total charges, hundred thousand dollars - Average total charged for a visit in hundred thousand dollars.

Appendix 3.B: ICD-9-CM diagnoses coding**Food allergies:**

477.1 - Allergic rhinitis due to food

558.3 - Allergic gastroenteritis and colitis

692.5 - Contact dermatitis and other eczema due to food in contact with skin

693.1 - Dermatitis due to food

995.6 - Anaphylactic shock due to adverse food reactions

995.7 - Other adverse food allergic reactions not elsewhere specified

988 - Toxic effect of mushrooms, berries, fish and shellfish etc.

V15.01 - Allergy to peanuts

V15.02 - Allergy to milk products

V15.03 - Allergy to eggs

V15.04 - Allergy to seafood

V15.05 - Allergy to other foods and food additives

Non-Food allergies:

Having symptoms common in food allergies:

Asthma and Bronchitis:

493.0 - Extrinsic asthma

493.9 - Bronchial allergic non-specified asthma

Skin Reactions:

691.8 - Other atopic (allergic) dermatitis

692.8 - Dermatitis due to cosmetics, metals and jewelry, animal hair

708.0 - Allergic urticarial (hives)

Allergy to drugs:

525.66 - Allergy to existing dental restorative materials

995.0 - Allergy to drugs and medical substances

995.2 - Unspecified adverse reaction to drugs taken internally (including correct and unspecified medical substances)

V14 - Allergy to medicinal agents

V64.04 - Allergy to vaccine and components

Having symptoms rare in food allergies:

Alveolitis and pneumonitis:

495 - Extrinsic allergic alveolitis and pneumonitis

Rhinitis:

477.0 - Allergic rhinitis due to pollen

477.2 - Allergic rhinitis due to animal hair and danger

477.8 - Allergic rhinitis due to other allergen

477.9 - Allergic rhinitis unspecified

Other allergies:

287.0 - Allergic purpura

372.05 - Acute atopic conjunctivitis

372.14 - Chronic allergic conjunctivitis

495 - Extrinsic allergic alveolitis and pneumonitis due to inhaled organic dust particles

V15.06 - Allergy to insects (including insect sting allergy and allergy to insects' protein)

V15.07 - Allergy to latex (results from inhaling or direct skin contact to latex proteins)

V15.08 - Allergy to radiographic dye

Unspecified Allergies:

995.3 - Allergy, unspecified

V15.09 - Other allergy, other than to medicinal agents

Control non-allergy diagnoses:

Respiratory system:

Asthma:

493.1 - Intrinsic asthma

493.2 - Chronic obstructive asthma

493.8 - Other forms of asthma

Bronchitis:

466 - Acute bronchitis and bronchiolitis

490 - Bronchitis, not specified as acute or chronic

491 - Chronic bronchitis

494 - Bronchiectasis

Pneumonia:

480 - Viral pneumonia

481 - Pneumococcal pneumonia (Streptococcus pneumonia)

482 - Other bacterial pneumonia

483 - Pneumonia due to other specified organism

484 - Pneumonia in infectious diseases classified elsewhere

485 - Bronchopneumonia, organism unspecified

486 - Pneumonia, organism unspecified

Rhinitis and Sinusitis:

472.0 - Chronic rhinitis (excluding allergic rhinitis)

473 - Chronic sinusitis

461 - Acute sinusitis

Pharyngitis:

472.1 - Chronic pharyngitis

472.2 - Chronic nasopharyngitis

460 - Acute nasopharyngitis (common cold)

462 - Acute pharyngitis including infective and bacterial cases

Tonsillitis:

463 - Acute tonsillitis including infective and bacterial cases

474 - Chronic disease of tonsils and adenoids

Skin Reactions:

Dermatitis:

691.0 - 691.7 - Non-Allergic Dermatitis

692.0 - 692.4, 692.6-692.9 - Non-Allergic Contact Dermatitis

693 - Dermatitis

Other Skin Reactions:

708.1 - 708.9 - Non-allergic urticaria

110 - Dermatophytosis

054 - Herpes simplex

Other Diseases:

372.00 - 372.04, 372.10- 372.13, 372.15, 372.2 - 372.9 - Non-allergic conjunctivitis

316 - Psychic factors associated with diseases classified elsewhere including psychogenic asthma, dermatitis, eczema, urticaria

Appendix 3.C: Common Cross - Reactions between the Major Food Allergens and their Associates

Eight Major Food Allergens	Their Food Associates	Their Non-Food Associate
1. Seafood and fish	1. Frog meat, snails, crustaceans, mite	1. Mite allergy
2. Peanuts	2. Other nuts, legumes, Rosacea fruit	2. Lupine pollen, ragweed pollen, atopic dermatitis/ eczema, atopic asthma
3. Almonds, hazel nuts, walnuts	3. Other nuts, legumes, Rosacea fruit	3. Alder pollen, birch pollen; less common latex
4. Soy	4. Other legumes, nuts	4. Birch pollen
5. Milk	5. Veal	5. Atopic dermatitis/ eczema; atopic asthma
6. Egg	6. Same or different bird species	6. Atopic dermatitis/ eczema; atopic asthma

Sources: Heratizadeh et al. (2011), Boyce et al (2010), Garcia and Lizaso (2011).