Food Safety Modernization Act: More FDA Power to Solve a Sick Problem

Food-borne illness is one of the most understated problems in the United States, killing over 5,000 people annually, according to Robert Scharff, a reporter for the Produce Safety Project, and affecting nearly a quarter of the American population, which costs a staggering \$152 billion dollars in lost productivity and decreased life expectancy annually (Scharff). The real problem with food-borne illness, however, is that the Food and Drug Administration (FDA), which regulates all non-meat food in the United States, has no legal power to stop contaminated food before it reaches consumers. Their power to recall contaminated foods is limited at a mere suggestion, one which some food producers do not listen to: in 2009, despite the fact that the FDA found that peanuts produced by Westco Fruits and Nuts Inc. were contaminated with Salmonella, Westco refused to implement a recall of their product (Stephenson). A worse problem is the lack of funding within the FDA, which causes them to inspect a pitiful number of food facilities in America: the Center for Science in the Public Interest (CSPI) found in 2007 that only 0.2% of the millions of foreign imported shipments of FDA regulated food were actually inspected due to a lack of funding – it's no wonder a quarter of the population contracts a food-borne disease each year! (DeWaal). Thus, it is clear that the FDA not only lacks power, but also lacks funds, and this is a large reason that food-borne illness in the United States has been such a large problem.

The problem of food-borne illness is not a new one, but the FDA has historically had many problems regulating its budget, and thus the problem of food-borne illness has expanded as a result. Rufus Guthrie, who holds a Ph.D. In microbiology from Baylor University, Texas, reported that in 1992, about 12.5 million cases of food-borne illness occurred annually, costing a little over \$8 billion to the economy (Guthrie). As is reported by Scharff, however, the number of cases of food-borne illness have increased six-fold over the past twenty years, and the costs of these cases have increased twenty-fold. This increase can be attributed to a lack of FDA funding, which has caused the inspection rates of

foreign and domestic facilities to be unreasonably low. A Government Accountability Office report found that a 1989 FDA funding requirement report asked for much less funding than it ended up needing to operate its inspection of food and drugs that year, and even in 2008, the FDA underestimated its budget requirements by almost half a billion dollars (Dooren). Thus, it is clear that in order to tackle the problems of food-borne illness, our government must first tackle the problem of insufficient FDA funding, so that they can more regularly inspect food-producing facilities, which will prevent Americans from consuming non-inspected, non-regulated, contaminated foods.

In response to the large number of annually reported illnesses and insufficient FDA funding, the FDA Food Safety Modernization Act (bill S.510) was introduced by Richard Durbin [D-IL] during the current 111th congress. If passed, the bill will allocate money and resources for the FDA to take a much larger stance in the regulation of food manufacturers than was financially and legally possible in the past. Rather than being limited to inspect or test a food-producing facility after a bacterial infection is reported to exist in the facility, if the act is passed, the FDA will be required to regularly test and inspect large facilities for food-borne diseases – before they spread and affect people. The bill will also give the FDA the power to mandate a recall on food products it finds to be infected, which will further ensure that less food-borne illnesses will pass on to the American consumer. The bill is actually quite likely to pass, because it has a large support base in the Senate, amongst both Democrats and Republicans. Its widespread support is a function of how many cases of illness can be prevented – potentially millions, because the FDA will be able to inspect facilities regularly, thus promising that food manufacturers will be safer in general after the passage of this bill – as well as the billions of dollars that will be saved from these prevented cases of illness – mostly from health-care and lost-productivity costs – that far outweigh the cost of implementing the bill in the first place. Thus, the FDA Food Safety Modernization Act is the best possible solution to the problem of food-borne illness in America because it gives the FDA more power and resources to inspect food-production facilities and prevent disease, which is a feasible

solution because of widespread support in the Senate, and will potentially prevent millions of people from getting sick annually, while saving our economy billions of dollars in lost productivity costs due to food-borne illness.

Although the three points just mentioned are clear reasons to implement S.510 immediately, the bill still receives some heavy opposition from several organizations, one of the most prominent being the Farm-To-Consumer Legal Defense Fund (FTCLDF). The FTCLDF lists several major reasons on their website why the increased recall power and funding for the FDA is a bad solution to the problem of unsanitary foods in America. The foremost of these is that the FDA already has adequate powers to inspect food products, and yet does not take advantage of it: for example, the FDA "inspects only 1% of food coming into this country from outside our borders" (Vote No on Cloture). While the FDA truly does have the power to inspect foreign food imports, the problem of this extremely low inspection rate is a lack of money, rather than a lack of concern. Indeed, Caroline DeWaal, the director of food safety for the Center for Science in the Public Interest, claimed that "these declines in [foreign and domestic FDA] inspections can be traced to an ongoing funding shortfall in the food safety program estimated in the hundreds of millions of dollars" (DeWaal). The FTCLDF's argument is thus invalid, because without money and resources, the FDA truly doesn't have sufficient power to inspect the facilities it oversees. The FTCLDF also argues that because S.510 is more lenient on foreign inspections, it "will only increase the amount of food imported into this country that does not meet our domestic standards" (Vote No on Cloture). However, the FTCLDF is clearly uninformed, as the bill calls for the same rate of increase for inspections on foreign facilities as it does for domestic ones; in fact, the bill treats foreign and domestic facilities exactly the same, even defining "the term 'facility' [as] a domestic facility or a foreign facility" (U.S. Senate). The last FTCLDF argument against S.510 is that because the FDA refuses "to require labeling for genetically-modified foods, ... this bill does not ... truly protect public health" (Vote No on Cloture). This is a clear Ad Hominem argument, because the FTCLDF tries to claim

that increasing the FDA power to recall is a bad idea solely on the grounds that they have some other, totally unrelated controversial policies in place. Furthermore, the FTCLDF is involved in a lawsuit with the FDA over the legalization of unpasteurized milk, and thus the organization clearly has a large bias against the FDA in the first place – this influential organization may have ulterior motives for slandering the FDA and its policies. Thus, because the FTCLDF is clearly biased against the FDA, and because its major arguments are uninformed, I must conclude that S.510 cannot be discredited on the basis of the FTCLDF's opposition, and that S.510 is still the best solution to the problem of unsanitary foods in America.

Although the Food Safety Modernization Act is the best way to solve the unsanitary food problem, another bill – S.1527, the Unsafe Meat and Poultry Recall Act – also addresses the problem, but with an alternate solution. Rather than give the FDA the ability to mandate food recalls, S.1527 attempts to give mandatory recall powers to the USDA. While S.1527 and S.510 could be implemented simultaneously, S.1527 essentially claims that the problem of unsanitary foods lies with insufficient recall abilities of the USDA, while S.510 claims the problem lies with the recall abilities of the FDA. There are several reasons why S.510 is a better solution to the problems in our food system. The first of these is that S.510 backs up FDA recall abilities by allocating millions of dollars of "resources needed [by the FDA] to effectively implement the programs and practices [such as more frequent factory inspections]... over a 5-year period" (U.S. Senate). This is a necessary aspect of mandatory recall abilities, as it gives the FDA a better perspective than before on which foods should be recalled. S.1527, by contrast, does not call for the allocation of any resources, and uses the same methods as before to inspect and analyze food manufacturing facilities. Thus, it is not clear that the USDA will use their recall powers any more effectively than before under S.1527, while it is a large part of S.510 to increase the efficacy of recall powers. In relation to this point, the American Veterinary Medical Association (AVMA), which analyzes and reviews nearly all animal-related bills in Congress, "believes that the

current system of voluntary recall [under the USDA] is effective and does not negatively impact public health [and thus believes S.1527] is not warranted" (Issue Brief: S.1527). Despite this, AVMA is in support of S.510, implying that the voluntary recall system within the FDA is ineffective, and can be solved by S.510. A last reason that S.1527 is much less effective than S.510 is that, according to The Center for Science in the Public Interest, the FDA regulates "80 percent of the food supply", meaning that only 20% of the food supply in America is regulated by the USDA (DeWaal). Thus, it is more important to consider problems within the FDA, which regulates four times as much food as does the USDA; S.510, if implemented, will solve a much larger proportion of the food-borne illness problem than S.1527. Thus, I conclude that S.510 is a much more effective plan in solving the problems of insufficient food safety in America than S.1527, because it is a more detailed and effective solution.

The first reason that S.510 is the best solution to the problem of food-borne illness is that it is highly feasible to implement because of widespread, bipartisan support within the Senate. On the GovTrack web-page for S.510, over twenty-one senators are listed as being cosponsors for the bill; the even more unusual thing about this is that over a third of these senators are Republicans, despite the bill being a Democratic solution to the problem of food-borne illness (S.510). Because any bill needs to pass with a two-thirds majority in the Senate, bipartisan support for a bill is one of the most important factors in its passage into a law, and thus I must conclude that this fact alone contributes heavily to the feasibility of the bill. Eighteen amendments were also made to the bill last month by various senators and cosponsors, also showing that a large portion of the Senate is generally interested in keeping this bill alive, by changing it to gain a wider appeal (S.510). In fact, after these amendments were made, the bill actually did pass in the Senate, with 73 senators supporting the bill, as a further testament to the feasibility of S.510 actually becoming a law. However, not all of the bill's advocates believe that S.510 will be passed – despite the bill's large support base – due to the fact that the amendments made to the bill require it to be passed through the House of Representatives again for approval, and then to be

passed onto the president for approval, all which must happen by the end of 2010 – lest the bill die before becoming a law. For these reasons, David Acheson, former associate commissioner of foods at the U.S. Food and Drug Administration, believes that "If S. 510 does not pass [this year], we will not see food safety legislation again this decade" (Bottemiller). I disagree with Acheson however, because last year, Senator Durbin – who introduced S.510 initially – introduced S.3385, which has the exact same title and legislation as S.510, but did not pass because of a lack of notoriety. Considering that S.510 has plenty of support within the Senate, if the bill does not pass this year, I believe that Durbin will introduce the same exact bill again next year, which the Senate should definitely support again, and which will have more time to reach the president. Thus, because of widespread support and the relentless efforts of Senator Durbin, I believe that the legislation of this bill will pass – if not in the 111th congress, then in the 112th.

The second reason that S.510 is the best solution to the problem is that, because it allocates resources to increase the inspection rates of facilities under FDA regulation, millions of cases of foodborne illness will be prevented annually. This year, 1,500 reported cases of Salmonella enteritidis were linked to tainted eggs produced by Wright County Egg and Hillandale Farm. However, the FDA began inspection of these two egg producer's facilities months after the outbreaks had affected people, checking compliance with "new federal egg safety rules that were written well before the current outbreak"; in fact, these facilities had never been inspected by the FDA before (Neuman). This is not abnormal under current FDA practices, which only calls for the inspection of approximately 7,400 facilities annually, out of hundreds of thousands of these facilities throughout the United States (Congressional Budget Office Cost Estimate). But if S.510 is passed, then over 50,000 facilities will be inspected annually by the year 2015 – a minimum of one inspection every five years for every facility in the United States – which will essentially eliminate occurrences such as these, where filthy conditions that incubate food-borne illnesses are not caught early on, thus affecting thousands of people

(Congressional Budget Office Cost Estimate). An important detail to note when considering that only 1,500 cases were reported is that, according to the Center for Disease Control, "an estimated 5% of all cases [of food-borne illness] are reported", and thus it is likely that up to 30,000 people were actually affected (Centers for Disease Control and Prevention). If S.510 were implemented, 30,000 cases of food-borne illness could have been prevented by just this single outbreak alone. Considering that S.510 calls for the inspection of 7 times more facilities than are currently inspected per year, it is clear that many more of these outbreaks will be prevented before they occur than just this particular one. With over 76 million Americans annually affected by food-borne illnesses, and with a majority of these cases caused by foods under FDA regulations, the implementation of S.510 should prevent a hefty proportion of these cases, which amounts to millions of people annually (Scharff). Thus, because S.510 will directly prevent millions of cases of food-borne illness annually, I must argue that it is the best possible solution to the current food-borne illness problem.

The third reason that S.510 is the best solution to the problem of unsanitary produce is because it will save our economy billions of dollars, which will offset the costs of implementing the bill and will ultimately save money. The cost of implementing the bill is estimated by the Congressional Budget Office as being a daunting 1.4 billion dollars for the years 2011-2015, or an average of about 300 million dollars per year (Congressional Budget Office Cost Estimate). The majority of this cost goes towards inspecting every high-risk facility - including all food processing or manufacturing facilities in America - once by 2015, and every three years thereafter, which is much, much more often than inspection rates have been historically. Although spending over a billion dollars to increase FDA inspection abilities might seem absurd considering that the current state of the American economy is poor, this spending actually constitutes one of the greatest investments in American history. As I mentioned at the beginning of this paper, the cost of food-borne illness to the American economy is over \$150 billion dollars, and so if even a fraction of this cost can be defrayed by mandatory adjustments to current food manufacturing

facilities - which are known to promote disease outbreaks - the bill will net a multi-billion dollar return on the initial investment (Scharff). This point is arguable, however, because the FDA does not regulate livestock, and thus bacteria such as Campylobacter and Salmonella, which generally originate from livestock and constitute a major portion of the food-borne illness costs in America, are not covered under S.510. However, even if just half of the food-borne illness costs are attributed to foods under FDA regulation, then over 75 billion dollars of lost money will be substantially decreased annually, which is still far higher than the cost to implement the bill. Therefore, implementing S.510 provides more benefits than costs, and is a good investment in our economy, even just from a purely monetary standpoint.

The Food and Safety Modernization act may very well be one of the most important bills ever proposed in concern to the health and economic well-being of America, in terms of the magnitude of its solution. This year, in light of a recession, the economic drain of food-borne illness can no longer be tolerated: action must be taken in order to lessen the burden of sickness in this country, if not just for economic reasons, then for the well-being and safety of the American populace. The bill already has the widespread, bipartisan support of the Senate, but because of technicalities and a lack of time, S.510 may not pass this year. However, I am a firm believer that the legislation of this bill will appear again next year if S.510 does not pass, just as S.510 was reintroduced after its legislation showed a poor performance in the 110th Congress; a problem as large as food-borne illness is not so easily silenced or forgotten. If this is the case, there is no doubt that America will come to its senses, show its support, and truly ensure itself a healthier future, devoid of the utterly sick problem of food-borne illness.

Citations

- Congressional Budget Office Cost Estimate: S.510. Congressional Budget Office, 2010. 7 Dec. 2010.
- <u>Issue Brief: S. 1527 Unsafe Meat and Poultry Recall Act</u>. American Veterinary Medical Association. 2009. 7 Dec. 2010.
- S. 510: FDA Food Safety Modernization Act. Civic Impulse, LLC. 2009. 8 Dec. 2010.
- <u>Vote No on Cloture & Oppose S.510</u>. Farm-to-Consumer Legal Defense Fund. 2010. 7 Dec. 2010.
- Bottemiller, Helena. "Election Unlikely to Change S. 510 Fate in Senate." <u>Food Safety News</u> 3 Nov. 2010: 8 Dec. 2010.
- Centers for Disease Control and Prevention. <u>Food-Related Illness and Death in the United States</u>. Paul S. Mead, et. al. Atlanta, Georgia: Centers for Disease Control and Prevention, 1999. 7 Dec. 2010.
- DeWaal, Caroline S. <u>Going Beyond FDA's Food Protection Plan: Modernizing U.S. Food Safety Law.</u>
 PDF. Washington, DC: Center for Science in the Public Interest, 4 Dec. 2007.
- Dooren, Jennifer C. "GAO: FDA Can't Determine Its Funding Needs." The Wall Street Journal 20 Jul 2009: 8 Dec. 2010.
- Guthrie, Rufus K. Salmonella. Boca Raton, FL: CRC Press, 1992.
- Neuman, William. "Egg Farms Violated Safety Rules." <u>The New York Times</u> 30 Aug. 2010: 7 Dec. 2010.
- Scharff, Robert L. <u>HEALTH-RELATED COSTS FROM FOODBORNE ILLNESS IN THE UNITED</u>

 <u>STATES.</u> PDF. Washington D.C.: Produce Safety Project, 3 Mar. 2010. 17 Oct. 2010.
- Stephenson, Emily. "Provider Refuses FDA Request to Recall Possibly Contaminated Peanut Products." infoZine 26 Mar. 2009: 7 Dec. 2010.
- United States. Cong. Senate. 111th Congress, 1st Session. S. 1527, Unsafe Meat and Poultry Recall Act [introduced in the U.S. Senate; 28 July 2009]. 111th Cong., 1st sess. Congressional Bills, GPO Access. Web. 7 Dec. 2010.

United States. Cong. Senate. 111th Congress, 1st Session. *S. 510, Food Safety Modernization Act*[introduced in the U.S. Senate; 3 March 2009]. 111th Cong., 1st sess. Congressional Bills, *GPO Access*. Web. 7 Dec. 2010.