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July 26, 2022

The Honorable Frank Pallone, Jr.
Chairman
Committee on Energy & Commerce
United States House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Diana DeGette
Chair, Subcommittee on Oversight
Committee on Energy & Commerce
United States House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Pallone and Subcommittee Chair DeGette:

Thank you for the opportunity to respond to House Committee on Energy and Commerce's questions for the record for the committee hearing on May 25, 2022. Abbott Nutrition's ("Abbott" or the "company") responses are attached.

The company reserves the right to supplement its response, if appropriate.

Sincerely,

Thomas Evers
Vice President, U.S. Government Affairs

TE:taw

Attachment

cc: The Honorable Cathy McMorris Rodgers, Ranking Member
Committee on Energy & Commerce

The Honorable H. Morgan Griffith, Ranking Member
Subcommittee on Oversight

Attachment—Additional Questions for the Record

Subcommittee on Oversight and Investigations
Hearing on
"Formula Safety and Supply: Protecting the Health of America's Babies"
May 25, 2022

The Honorable Frank Pallone, Jr. (D-NJ)

1. On June 15, 2022, Abbott released a statement that it stopped production of its EleCare specialty formula because of damage to its Sturgis plant from recent floods. Please provide an update on Abbott's efforts to remediate the flood damage, any plans to further insulate the facility from water damage, Abbott's assessment of when the company anticipates being able to re-start production at the facility, and a description of how the current pause affects the company's broader response to the shortage.

On June 13, 2022, a severe weather event caused approximately 1.45 inches of total rain to fall in a 25-minute period in Sturgis, Michigan, with a peak hourly rate of 4.46 inches/hour. The Sturgis city storm system was overwhelmed, and a city backup of the drainage system led to flooding in the Sturgis facility. Abbott's Sturgis facility has a bifurcated system whereby storm water is evacuated from the site via an Abbott outflow into an Abbott retention system and a second system which flows into City of Sturgis storm water collection.

Following the storm, Abbott communicated with the U.S. Food and Drug Administration (FDA) and began to remediate the flood damage, and all remediation was completed by July 1, 2022. Abbott re-started production of specialty formulas at the facility later on the same day, July 1, 2022. Abbott is redesigning its system such that storm water which currently flows from the site to the city storm water system (which became overwhelmed causing site outflow to back up) will be disconnected from the city system and re-routed to an Abbott site storm basin. The storm event caused approximately 3 weeks of delay in the restart.

2. How, if at all, does Abbott plan to communicate with FDA regarding future supply-chain disruptions that may impact the supply of formula or other FDA-regulated goods?

Abbott has communicated and plans to continue to communicate with FDA regarding future supply-chain disruptions through various forums including emails, telephone calls and/or meetings. If FDA develops a formal process, Abbott will follow that process to communicate.

The Honorable Diana DeGette (D-CO)

1. On June 8, 2022, *several outlets* reported that the Department of Labor's (DOL) Occupational Safety and Health Administration (OSHA) shared a complaint with Abbott from an Abbott employee detailing various safety and sanitation concerns at the company's Sturgis, Michigan plant in February 2021. In addition to providing a copy of the complaint to the Committee, please provide responses to the following:

    a. Did Abbott receive such an OSHA complaint from DOL and if so, on what date?

    b. Who, including names and titles, within the company was charged with handling the complaint?

    c. What role, if any, did Abbott play in OSHA's investigation to the complaint, including any site investigations, interviews, or formal responses to and from OSHA?

    d. What, if any, action has Abbott taken in response to the February 2021 OSHA complaint? If no action was taken, please provide an explanation as to why not. In addition, please provide a description of Abbott's standard procedures for investigating complaints receives from OSHA, and whether or not these procedures were followed in investigating the complaint.

A former employee who had been terminated in 2020 (the "Complainant") initiated a legal process pursuant to which the Complainant sought damages and reinstatement of employment. In connection with that legal process, Abbott received notice that it was the subject of an FDA Food Safety Modernization Act ("FSMA") Complaint from OSHA in February of 2021. The matter was handled by Abbott's employment counsel, who cooperated with OSHA as OSHA conducted its investigation.

This is an ongoing administrative legal proceeding.

The Honorable H. Morgan Griffith (R-VA)

1. The CDC notes that *Cronobacter* is a germ that is naturally in the environment. Is it common for Abbott to detect *Cronobacter* in its manufacturing facilities?

Cronobacter is occasionally detected in the environment of infant formula manufacturing facilities, including Abbott facilities.

    a. If so, what actions do your facilities take when it detects *Cronobacter* or other bacterium?

Abbott facilities undertake an investigation and intensified sanitation measures when *Cronobacter* or another pathogen is detected in the environment, summarized as follows:

- The operations team cordons off the affected area to limit foot traffic and applies sanitizer to any entrances or exits of the affected area.
- The microbiology team takes environmental investigational baseline swab samples prior to cleaning the affected area to help understand the source and spread of the pathogen.
- An investigation is conducted, and actions are taken to address the source.
- After the investigational environmental swab samples are collected, deep cleaning of the area is performed, followed by sanitization of the area.
- An inspection of the areas is conducted.
- The microbiology team takes environmental post-cleaning vector swab samples to confirm that the pathogen has been remediated.
- The area of the initial pathogen detection must have three microbe consecutive passing test results before the area will be reopened.
- Using all the available information and data, a root cause analysis is conducted, and impact to product is assessed.
- For non-product contact areas, depending on the results of the impact assessment and the root cause analysis, production may be stopped.

b. Based on Abbott's understanding, can an infant formula manufacturing plant be in compliance with FDA requirements while occasionally finding environmental samples with *Cronobacter*? Why or why not?

Yes. In the preamble to the infant formula Good Manufacturing Practices ("GMP") final rule, FDA indicated that the agency was not setting a zero tolerance for any microorganism in infant formula processing plants ("FDA does not agree that the Agency is setting a zero tolerance for any microorganism either in infant formula or in the formula processing environment"). 79 Fed. Reg. 7934, 7990 (Feb. 10, 2014) at comment 153. Accordingly, there is a recognition by FDA that occasionally, companies may detect microorganisms such as *Cronobacter* in infant formula processing environments without violating FDA's regulations. The key is whether there are adequate controls in place to ensure that the infant formula does not become adulterated due to the occasional presence of *Cronobacter* in the environment. Environmental monitoring for *Cronobacter* is one example of an in-process control that is used by infant formula manufacturers like Abbott to verify the effectiveness of cleaning and sanitation activities.

2. Please describe the type of routine testing that Abbott conducts at its manufacturing facilities, including what Abbott is testing for and how often the testing is conducted.

As it relates to microbiological testing, Abbott Sturgis conducts routine environmental monitoring, testing of incoming raw material ingredients, testing of in-process product, and testing of finished product, as follows:

- Routine environmental testing:
    - Abbott performs microbial tests of the environment. Depending on the test sample, the sample is tested for *Salmonella*, *Listeria*, standard plate count (SPC),

Enterobacteriaceae (EB) and *Cronobacter* spp. Different areas of the environment are tested at different frequencies depending on the proximity to the manufacturing of product.
    - Abbott has increased the frequency of routine environmental testing at its Sturgis, Michigan facility.
- Testing of incoming raw material ingredients:
    - Testing requirements for raw material ingredients depend on the original source of the raw material, the ingredient manufacturing process, the manufacturing of the finished product, and the intended use of the finished product.
    - Examples of the microbiological testing for the major ingredients that are used for dry blending into infant formula powder (*e.g.,* proteins, carbohydrates, fats, and stabilizers that are typically agriculturally sourced) include *Cronobacter* spp., *Salmonella*, *Listeria monocytogenes*, Enterobacteriaceae (EB)/ coliform, *Bacillus cereus*, coagulase positive *Staphylococcus aureus*, and standard plate count (SPC).
    - Testing variations must be approved by the Abbott Nutrition Division Microbiology team.
    - Abbott has increased the routine testing of incoming raw material ingredients at its Sturgis, Michigan facility.
- Testing of in-process product:
    - Every batch of powdered infant formula is tested during processing for Enterobacteriaceae (EB) and standard plate count (SPC). For processes with 2 heat inactivation steps, samples are collected at 5 time points during the production of each batch. For other products, samples are collected at 3 time points during the production of each batch.
    - Additional in-process samples are collected at 2 time points, 5 times per quarter.
    - Abbott has increased the routine testing of in-process product at its Sturgis, Michigan facility.
    - For example, Abbott Sturgis also collects approximately 900 g of in-process powder with an autosampler, taken from throughout the batch, for testing.

- Testing of finished product:
    - Every batch of finished powdered infant formula is tested for *Cronobacter* spp. and *Salmonella* spp. prior to release, in the manner specified in FDA regulations at 21 C.F.R. § 106.55.
        - For example, FDA regulations at 21 C.F.R. § 106.55 specify that for *Cronobacter* spp., 30 samples of 10 g each shall be tested, and for *Salmonella* spp., 60 samples of 25 g each shall be tested.
        - Abbott Nutrition Sturgis's current testing exceeds the regulatory requirement by testing composite samples pulled from 180 containers for both *Cronobacter* spp. and *Salmonella* spp.
    - At the Sturgis, Michigan facility, Abbott's current routine testing also exceeds FDA requirements for non-infant formula powder. Abbott is testing non-infant formula product for *Cronobacter* spp. prior to release, although it is not required by FDA regulations.

a. What is Abbott's process for addressing any adverse findings during its routine testing?

- For environmental testing, please see the response to question 1(a) above.
- For incoming raw material ingredients, in the event of a confirmed positive *Cronobacter* spp. or *Salmonella* spp. result, the Site Quality Director and Global Supplier Quality Assurance are notified. The affected raw material ingredient is isolated and the shipment is rejected. The impact of the event is assessed, and an investigation is conducted. The supplier is contacted to determine if the positive result is an isolated event, or if there is the potential for the pathogen to be present in additional shipments and/or supplier lots of the ingredient. If the initial investigation indicates that the pathogen issue may extend to additional material of the same or other supplier lots, all affected sites are contacted with specific instructions to assess the extent of the issue and prevent the release of questionable materials.
- For in-process product, in the event of a confirmed positive *Cronobacter* spp. or *Salmonella* spp. result, the Site Quality Director is notified. The affected product and any potentially affected product is isolated and placed on a quality hold. The site qualified individual and operations area personnel will ensure an investigation of an adverse finding determines the cause(s) of the excursion and/or the need for further action.
- For finished product testing, in the event of a confirmed positive *Cronobacter* spp. or *Salmonella* spp. result in finished product, production will be stopped and environmental sampling will be performed on the manufacturing equipment and areas. The affected finished product will be disposed of. An investigation will be conducted to determine whether other batches could be impacted. Batches that touch the same equipment immediately before or after the impacted batch will be tested (using increased sampling amounts) for the presence of the microorganism confirmed in the initial batch.
- For the Sturgis facility, under the terms of the consent decree, Abbott Nutrition is required to report any confirmed *Cronobacter* spp. environmental results to the FDA within 24 hours. Abbott Nutrition is also required to report any confirmed *Cronobacter* spp. or *Salmonella* spp. results in raw material ingredients or in product to FDA and to cease production.

a. For example, who is notified of the adverse findings, is there paperwork that is created to document the adverse findings, are there corrective action plans put in place to address the adverse findings?

- Abbott has an approved Food Safety Plan and comprehensive Quality System that instruct on the handling of adverse findings. There are processes in place to document adverse findings in various types of records depending on the event.
- For example, at the Abbott Sturgis facility, when there is a positive test for a pathogen during environmental monitoring, the site microbiology personnel notify the quality leadership team, site staff, area owner, and global microbiology team. Microbiology personnel will complete a Corrective Action System Report, and a plan is put in place to address the adverse findings.

- When there is a positive test for a pathogen during testing of raw material ingredients, the Sturgis site microbiology personnel notify the quality leadership team. Microbiology personnel will complete a Corrective Action System Report. A plan is put in place to address the adverse findings.
- When there is an adverse finding during testing of in-process product, the Sturgis site microbiology personnel notify the quality leadership team, site staff, area owner, and global microbiology team. Microbiology personnel will complete a Corrective Action System Report. Corrective action plans are put in place.
- When there is a positive in finished product, the Sturgis site microbiology personnel notify the quality leadership team, site staff, area owner, and global microbiology team. Microbiology personnel will initiate a Quality Assessment to assure notification of the out of specification result to the Quality Systems group in addition to notifying within routine production meetings and the Abbott Nutrition leadership team. Corrective action plans are put in place.

b. If paperwork is created as a result of any adverse findings, does that paperwork come to your attention?

The Quality System includes an approval process defining the responsibilities for approvals of the documents or records generated. In addition, adverse events involving pathogenic bacteria are communicated to multiple levels of the Abbott Nutrition leadership team.

3. Other than the U.S., for which other countries does Abbott's Cootehill, Ireland, plant provide infant formula product?

In addition to the United States, the Abbott Nutrition facility provides infant formula to 55 other countries.

a. When did the shipments from the Ireland facility into the U.S. begin?

The Abbott Nutrition Cootehill site is registered with the FDA and began shipments to the United States in 2021. The Cootehill site increased the volume of product to the United States after the Sturgis event in 2022.

b. Since the shipments started, how much additional product has Abbott been able to produce and ship into the U.S. from its Ireland facility?

Prior to the Sturgis event, the 2022 Cootehill Site Production Plan was to supply the United States with approximately 20 million pounds of infant formula, which is now planned at approximately 33 million pounds for 2022. Since the event, the Cootehill facility has increased the monthly production for the United States from 1.3 million pounds to just over 3 million pounds. Year to date in 2022, Abbott has imported more than 14 million pounds of infant formula into the United States.

4. Has Abbott submitted infant formula enforcement discretion requests to FDA?

If so, please explain what those requests were, when they were made, and whether FDA has responded to those requests.

Abbott has made 5 submissions to the FDA for enforcement discretion to import non-U.S. product labeled from its other global facilities. To date, the FDA has granted enforcement discretion for 4 of those submissions for product from Abbott plants in Spain and Ireland. Abbott has already imported approximately 45,000 pounds and has plans to produce and import up to an additional 1 million pounds in the upcoming weeks.

5. There are reports of challenges in the first 3-4 days of Abbott's recall in ensuring affected products were removed from retailer's shelves. For example, confusion and poor direction on identifying affected batch and lot numbers led to retailers pulling more infant formula off the shelves than was needed. It is our understanding that Abbott sent third-party auditors into retailers to mitigate this confusion. At what point before the February 17th and 28th formula recall announcements did Abbott begin outreach to retailers with instructions on how to safely remove affected products from shelves?

Abbott initiated communication with retailers on how to remove product promptly after the recall announcement on February 17th. Abbott communicated the scope of the recall and identifying information regarding the impacted lots. Retailers proceeded to remove product using this information and following the policies they have in place for executing recalls. Third-party brokers were used to ensure that impacted product had been removed. However, it appears that customers are documenting all product in their inventory in their product response form, i.e. they intend to return recalled and non-recalled lots. This type of response is not unexpected as it is easier for them to return all product at the item level rather than segregating by lot.

a. When the recalls were issued, did Abbott share informational materials with retailers on alternative sources of infant formula and guidance on purchase limits for formula products?

Abbott did not share informational materials with retailers on alternative sources of infant formula. Abbott did discuss the topic of purchase limits with retailers, but ultimately deferred to the retailer's established policies.

6. When did the federal government first start to implement waivers and flexibilities to allow for WIC consumers to purchase substitute infant formula products?

Abbott began offering competitive rebates in February 2022. The United States Department of Agriculture ("USDA") Food and Nutrition Service immediately offered waivers to state agencies allowing for participants in the Special Supplemental Nutrition Program for Women, Infants, and Children ("WIC") program to more easily exchange their recalled formulas. Since then, USDA has offered additional waivers that allow for imported products to be issued through the WIC program even if they do not meet the WIC standards for iron and calories.

a. Are your companies communicating with the various state, territory, and tribal WIC agencies to help facilitate substitute products?

Yes, Abbott is in regular communication with the states and tribes to ensure all products they would like to utilize are set up to receive rebates.

7. What has this recall made clear to Abbott about its infant formula manufacturing footprint moving forward? Does Abbott have plans to make investments to build additional infant formula manufacturing capacity? Why or why not?

Please see answer to Rep. Burgess' question 3a, below, about Abbott's investments in its formula manufacturing capacity.

The Honorable Michael C. Burgess, M.D. (R-TX)

1. Mr. Calamari, I understand that the baby food market was strained far before the Sturgis facility shut down in February.

    a. What was the situation like before the voluntary recall and shutdown of the Sturgis facility?

The infant formula market started to experience elevated levels of growth in the third and fourth quarters of 2021. This growth was higher than historical levels and was greater than what long-established key market factors of birth and formula feeding rates would have indicated. Research conducted to inform understanding of these dynamics suggests that consumer households were purchasing infant formula at elevated levels in 2021 and extending into 2022.

2. The FDA concluded their inspection of the Sturgis, Michigan, Abbott facility on March 18, 2022, and Abbott responded to this investigation and began making changes on April 8, 2022.

    a. Why did it take over a month to enter into the consent decree on May 16, 2022?

Abbott's Response to FDA's March 18, 2022 Form 483 Observations was submitted to FDA on April 8, 2022. The Response to the Form 483 Observations is a technical document setting out specific responses, corrections, and corrective actions in response to FDA's observations. It contained detailed information about actions that Abbott proposed to perform (and was already undertaking at the time) to remedy the FDA's Observations.

The Consent Decree is a legal agreement between the Department of Justice and Abbott. It is a separate document, with different provisions, that had to be separately negotiated.

3. Mr. Calamari, in considering next steps, we need to ensure something like this never happens again.

a. What are the recommendations that you have been given by the FDA and started working on?

To help make sure this does not happen again, Abbott plans to expand both capacity and redundancy. This will increase the nation's formula supply and create the needed redundancy to ensure the uninterrupted production of critical products like EleCare and metabolic formulas. Abbott will also continue to invest in upgrading its safety and quality processes and manufacturing equipment. In the meantime, the company will continue to invest heavily in building out its global manufacturing network and arranging for additional redundancies throughout its formula business globally. Abbott is devoting significant resources to ensure this never happens again.

b. What is Abbott doing to ensure American parents can trust the safety of their formula again?

The recall and shutdown of the Sturgis plant were appropriate steps taken out of an abundance of caution based on the information available to Abbott at the time. But the subsequent investigations have not established any link between Abbott's products and any infant illnesses. Genetic testing has not established a link between the environmental strains of *Cronobacter sakazakii* found in the Sturgis facility and any infant illnesses. And comparison of the genetic sequencing from patient samples that were available did not even match one another, indicating that the infections did not have a common source. Moreover, as part of the investigations, and in conjunction with the release of previously manufactured metabolic and other specialty formulas, Abbott has now tested more than 10,000 finished, sealed cans of Sturgis-manufactured products in 2022. Not a single test has confirmed positive for *Cronobacter sakazakii* or Salmonella.

Nevertheless, Abbott has made substantial improvements to the Sturgis facility, and enhanced its environmental and finished-product testing programs, so that parents can further be assured of the safety of all of the company's formula products, including those manufactured at Sturgis.

The Honorable Gary Palmer (R-AL)

1. Mr. Calamari, between the 2019 and 2021 inspections by the FDA, Abbott was aware of issues at the Sturgis plant ranging from inadequate pathogen testing procedures and mishandling of ingredients, packaging, and equipment to the presence of *Cronobacter* in the facility. Furthermore, you received complaints from parents and nurses that believed your product was making infants sick.

    a. Why did Abbott not immediately address these issues on your own, instead of waiting until the FDA got involved to correct these failings?

When Abbott becomes aware of an issue that requires correction, the team puts in place a plan to correct it, and then executes on that plan. For example, your question references "inadequate pathogen testing procedures," which appears to be a reference to the September 24, 2019 483 Observation following the 2019 inspection of the Sturgis facility. Regulation (21 C.F.R. § 106.55(e)) requires that infant formula manufacturers test 60 samples of 25 grams each for

Salmonella spp, and 30 samples of 10 grams each for *Cronobacter* spp. The Sturgis facility's testing program was in full compliance with both requirements, and required taking 60 25 gram samples from 30 different finished product containers (two samples from each container, one from the top and one from the bottom). Nevertheless, after discussing the issue with FDA, before the end of 2019, Abbott instituted a change to its procedure and retrained its staff such that, going forward, the required 60 samples would be taken from 60 different finished product containers. Abbott Sturgis's current protocol is to take 180 samples from 180 containers per batch.

Similarly, where internal testing finds *Cronobacter*, as happens with all manufacturers from time to time, the company immediately undertakes steps to determine the root cause and implement corrections and corrective actions. FDA then reviews those records during its inspections, all of which is documented in FDA's Establishment Inspection Reports. Abbott does not wait for FDA to become involved before issues are addressed.

2. Mr. Calamari, can you list each of the FDA observations found in the 2019 FDA inspection and what specifically Abbott did, if anything, to address each one?

FDA's Form 483 for 2019 contained a single observation related to the number of containers Abbott used to draw samples from for finished product testing. As described above, by the end of 2019 Abbott changed its procedures to begin taking each of the required 60 samples from a different container.

3. Mr. Calamari, it has been reported that in advance of the 2021 FDA inspection of the Sturgis plant, the FDA notified Abbott.

    a. How was Abbott notified? If by letter, please provide a copy of the letter. If by electronic message, please provide a copy of the message. If by phone or other method of communication, please provide a record of the conversation.

Abbott Nutrition Sturgis was notified by telephone.

    b. Who received the notification of the impending inspection?

The notification was received by the Director of Quality Assurance, Abbott Nutrition Sturgis.

    c. Were specific issues at the Sturgis facility included or mentioned in the notification of the FDA inspection?

No, specific issues were not communicated.

    d. If problems or issues were cited in the notification, what action did Abbott take to address those issues prior to the inspection?

N/A, no issues were communicated during the notification.

e. What Abbott employees were involved with the FDA prior to, during and after the inspection was completed?

No Abbott Sturgis employees had contact with the FDA related to the inspection prior to the inspection other than for questions related to COVID. But dozens of employees interacted with the FDA during the inspection to provide information regarding product packaging, manufacturing, processing, ingredient warehousing, maintenance areas, the warehouse and distribution center, labs, as well as front room and back room support, among others. The Director of Quality Assurance, Abbott Nutrition Sturgis sent written responses to FDA Form 483 observations via e-mail after the inspection was completed.

f. Did anyone at Abbott give input on the FDA's final inspection report? If yes, what was the substance of that input? Please provide a list of Abbott employees who worked with the FDA on the inspection report.

No. To our knowledge, FDA has not yet issued its final inspection report for the 2021 inspection of the Sturgis plant. However, FDA writes its own Establishment Inspection Report without input from the inspected facility personnel.

4. Mr. Calamari, following the release of the FDA inspection report, apparently serious health and safety concerns persisted at the Sturgis plant that resulted in a whistleblower report that ultimately resulted in the closure of the plant. Who at Abbott was aware that there were health and safety issues at the Sturgis plant that were not being addressed?

It appears that the document you are referring to was submitted to FDA by a former employee in October 2021, several months before FDA issued its Form 483 Observations in March of 2022. Abbott's quality system exists to address any health and safety concerns in real time. To our knowledge, FDA has not yet issued its final inspection report for the 2021 inspection of the Sturgis plant.

5. Mr. Calamari, in our hearing you agreed to provide the committee with the list of individuals who would have known about the serious process and health issues that existed at the Sturgis plant prior to the 2021 FDA inspection. Please use this question to formally provide that list.

Abbott's quality systems exist to address quality concerns in real time. To Abbott's knowledge, nobody at the company believed there were "serious process and health issues" that were not being addressed.

The Honorable Lori Trahan (MA-03)

1. Please describe the number of times that employees made internal complaints about safety.

Abbott takes product safety and compliance issues very seriously and has implemented numerous processes for employees to report any potential safety or compliance concerns they have. In fact, to make sure all concerns are raised and addressed, Abbott provides multiple pathways for reporting concerns, including but not limited to: (a) direct communication with supervisors, relevant managers, and Human Resources; (b) *daily* Quality Systems Tier Agenda meetings, which specifically provide an opportunity to elevate safety and/or quality concerns and to check on the status of any existing concerns; (c) Food Defense Awareness training in which employees are further encouraged and instructed to immediately report any food-safety concerns; (d) the Quality Assurance program which reinforces for employees that "if you see something, say something, do something," in addition to a variety of other policies and procedures which provide opportunities for employees to report any concerns to Abbott's Office of Ethics and Compliance, Human Resources Department, and Legal Division among other pathways. In addition to all of these reminders and pathways to report concerns, Abbott also trains employees to know that they can submit an *anonymous* tip or complaint through its SpeakUp program. Abbott made that forum available to employees at the Sturgis facility 24 hours a day, 7 days a week, and this was available to Complainant throughout the time period of employment. Given the multiple opportunities available for employees to raise issues, there is not a single source for quantifying them.