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Via Electronic Mail Only
(Hhuntley@cdc.gov and Paula.Kocher@cdc.hhs.gov)

Heather Huntley, Esq.
and Paula Kocher, Esq.
The Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30333

RE: Foodborne Illness Event

Ms. Huntley and Ms. Kocher:

As you know, we represent Chipotle Mexican Grill, Inc. ("Chipotle"). Thank you for speaking with us over the past two weeks. We know your time is valuable and we appreciate your willingness to review additional information on Chipotle's position concerning the Centers for Disease Control and Prevention's ("CDC") web updates. We want the public to have the most accurate information available, as does the CDC. We are concerned that certain web updates do not include that information clearly and concisely and actually misinform the public.

Beginning on November 4, 2015, the CDC posted periodic web updates concerning the *E. coli* O26 investigation, including the number of illnesses, epidemiological findings, and Chipotle's response. While the initial announcement and early updates were generally necessary and appropriate, the ongoing updates were not useful and did not serve to inform the public of a significant health risk. Rather, these updates misrepresented the *E. coli* O26 outbreak as ongoing and unnecessarily intensified the public's concern. Additionally, on December 4, 2015, the CDC issued a statement which was patently inaccurate.

We understand the importance of notifying the public of a significant health risk and also understand the importance of proving relevant and meaningful updates when there is an ongoing public health risk. However, each update must stand on its own as to whether there is a significant health risk that necessitates an update to the public.

We are not claiming that the CDC intentionally misrepresented certain information. However, certain web updates actually misinformed the public because they were confusing and unclear. A review of media coverage, citing to the CDC updates, reflects the confusion and inaccuracies. Despite no ongoing threat, with four weeks passing between the last exposure date and the most recent web update, the web updates did not serve to protect the public and, in fact, led to

inaccurate conclusions. For the reasons outlined below, these web updates do not conform with CDC guidelines, and Office of Management and Budget ("OMB") and Department of Health and Human Services ("HHS") regulations concerning the dissemination of information to the public.

CDC Guidelines

The HHS has enacted certain guidelines for the CDC's release of information to the public. See **Exhibit A**, *Guidelines for Ensuring the Quality of Information Disseminated to the Public, D. Centers for Disease Control and Prevention* ("CDC Guidelines"). The guidelines apply to information in all media, including electronic media. In addition, the guidelines apply to substantive information, including reports and similar materials, statistical information, statistical analyses, aggregated information by other programs, speeches, interviews, or expert opinions. *Id.*, II. Scope and Applicability of Guidelines for CDC, Covered Information. Therefore, these guidelines apply to the web updates disseminated by the CDC.

According to the CDC Guidelines, "[i]t is CDC's policy to ensure and maximize the **quality, objectivity, utility, and integrity** of information that it disseminates to the public." *Id.*, II. Scope and Applicability of Guidelines for CDC. The CDC Guidelines also state that the CDC strives "to provide information that **is accurate, reliable, clear, complete, unbiased, and useful.** We are committed to integrating the principle of information quality into every phase of information development, including creation, collecting, maintenance, and dissemination." *Id.*

The CDC Guidelines further address the agency's quality assurance process and the responsibilities concerning the CDC staff in regard to the dissemination of information. In accordance with the CDC Guidelines, the CDC "reviews the quality (including objectivity, utility, and integrity) of information before it is disseminated and treats information quality as integral to every step of the development of information, including its creation, collection, maintenance, and dissemination." Before information can be disseminated, it must meet standards promulgated by the CDC and HHS, including:

- **Utility:** CDC addresses utility, a measure of the usefulness of information products to its intended users, by staying informed of user needs through information product research and user needs assessment, user feedback, consultation with advisory committees, and conference participation.

- **Objectivity:** CDC provides assurance that information is accurate, reliable, and unbiased. Objectivity is achieved through existing review and clearance procedures and, in many cases, the peer review of disseminated information.

- **Integrity:** CDC assures the integrity of its data and information products through the enforcement of rigorous controls that protect against unauthorized access, revision, or corruption. Some of the controls used at CDC include access control, user authentication, encryption, access monitoring, provision of unalterable electronic content, and audit trails.

Id., V. Agency Quality Assurance Policies, Standards and Processes for Ensuring the Quality of Information Dissemination to the Public, A. Overview.

Web Updates

Chipotle has concerns that various web updates do not meet the standards promulgated by the CDC. Each web update must stand on its own and independently comply with the CDC guidelines, and it appears that many of the web updates do not.

The CDC's December 4, 2015 web update misinformed the public as to the current status of the outbreak. The CDC reported seven additional reported *E. coli* O26 cases, including one in Pennsylvania and one in Maryland. Specifically, the web updates states that, "Illinois, Maryland, and Pennsylvania have been added to this list of reporting illnesses, bringing the total to nine states." There is no dispute the Pennsylvania case has no connection to Chipotle. In addition, it was recently disclosed to Chipotle that the Maryland case has an "unknown" Chipotle connection. However, in the web update the CDC made no effort to advise the public that these ill individuals had no known contact with Chipotle. As such, the update erroneously exaggerated the outbreak and created needless confusion as to whether Pennsylvania and Maryland Chipotle restaurants were linked to *E. coli*. This premature release of information does not provide the public with the best information available and actually misinforms the public.

In addition, the update states, "Of the three most recent illnesses reported in November, only one ill person, whose illness started on November 10, reported eating at Chipotle Mexican Grill in

the week before their illness began." This sentence does not clarify where the three most recent illnesses were reported. Instead, it leaves the public, including the media, to speculate as to where these reported illnesses occurred. The manner in which the web update is phrased misleads the public to assume that the outbreak is linked to Chipotle restaurants in 9 states, and not 7 states. The following are a few of the many news headlines that demonstrate this point:

- CNN Headline: "Chipotle E. Coli outbreak now linked to illness in 9 states"
  - http://www.cnn.com/2015/12/04/health/chipotle-e-coil-update---now-9-states/
- ABC News Headline: "E. Coli Outbreak Linked to Chipotle Widens, With 52 Sickened 9 States"
  - http://abcnews.go.com/Health/coli-outbreak-linked-chipotle-widens-52-sickened-states/story?id=35586870
- CNBC Headline: "UPDATE 1 – Chipotle E. coli outbreaks broadens to 9 states, shares drop"
  - http://www.cnbc.com/2015/12/04/reuters-america-update-1-chipotle-e-coli-outbreak-broadens-to-9-states-shares-drop.html
- Huffington Post Headline: Chipotle E. Coli Outbreak Broadens to 9 States"
  - http://www.huffingtonpost.com/entry/chipotle-e-coli-outbreak-broadens-to-9-states_5661e4afe4b079b2818e830a
- Fortune Headline: Chipotle's E. Coli Outbreak Has Expanded to 9 States"
  - http://fortune.com/2015/12/04/chipotle-e-coli-outbreak-expands/
- Reuters Headline: "Chipotle E. coli outbreak broadens to 9 states, shares drop"
  - http://www.reuters.com/article/chipotle-mexican-ecoli-idUSWNAB09C1920151204

As evidenced by the news headlines, this disclosure of incomplete and unclear information has been extremely harmful. Chipotle has had the difficult task of coping with a strong public backlash concerning states which were incorrectly tied to the outbreak. In actuality, the individuals in Pennsylvania and Maryland had **no known connection to Chipotle**.

In addition, buried within the December 4, 2015 web update is the phrase: "47 (90%) of 52 ill people interviewed reported eating at a Chipotle Mexican Grill in the week before their illness started." The CDC fails to elaborate further. The web update does not seek to clarify what states those 5 people who did not eat at a Chipotle restaurant came from or when their illnesses were

reported. This is yet another example of why the December 4, 2015 web update was incomplete and unclear.

While the December 4, 2015 web update is arguably the most misleading, there are other web updates that also caused confusion about the true nature of the outbreak. For example, on November 4, 2015, the CDC reported thirty-nine cases of *E. coli* O26 throughout Washington and Oregon. In rapid succession, the CDC released two updates, on November 5, 2015, and November 6, 2015, that each identified only one new reported case of *E. coli* O26. Neither the November 5, 2015, nor the November 6, 2015 update informed the public of substantive developments in the *E. coli* investigation. Again, on November 9, 2015, the CDC reported one additional *E. coli* O26 case. The remainder of the November 9, 2015 update referenced a case of *E. coli* O26 in Minnesota **with no connection to Chipotle**.

In light of these circumstances, Chipotle does not believe the web updates between November 4, 2015, and November 6, 2015 provided the public with information that was clear and useful, as mandated by CDC regulations. Rather, the piecemeal release of information which does not inform the public of investigatory benchmarks or remedial steps by Chipotle only acts to create public panic. Moreover, it is our belief that most of the general public is not familiar with foodborne illnesses, and the inclusion of an unrelated case in a Chipotle-specific update is confusing.

Similarly, on November 20, 2015, the CDC reported six cases of *E. coli* O26 throughout four additional states. It does not appear that the information provided in this update was useful to the public. For over a month, the events of the *E. coli* O26 outbreak stemming from various Chipotle restaurants have been heavily publicized by national and international news outlets. Furthermore, such information has been widely disseminated through social media outlets, including Facebook and Twitter. The November 20, 2015 web update identified only a marginal number of cases within the same *E. coli* O26 event **during the same timeframe** as previously reported, and did not provide the public with information of which they were not already aware.

OMB and HHS Guidelines and Regulations

In addition to the CDC Guidelines, the OMB has issued government-wide guidelines to preserve the integrity of information disseminated by federal agencies to the public. *See* 67 F.R. 8402-01.

In 2002, and in response to the OMB mandate, HHS implemented its own protocol to ensure compliance with OMB mandate. As an operating component of the HHS, the CDC states that it "**will ensure** that disseminated information **meets** the **standards of quality** set forth by **the OMB and the HHS**." *Guidelines for Ensuring the Quality of Information Disseminated to the Public*, Scope and Applicability of Guidelines for CDC.

The HHS has adopted various guidelines for the dissemination of adverse information through the media. *See* 45 C.F.R. § 17.1 *et seq*. It is the CDC's position that these regulations do not apply to the CDC. However, the CDC is an operating division of the HHS, and we have researched this issue extensively and have been unable to find any document, order, directive, or statement that excludes the CDC from 45 C.F.R. § 17.1 *et seq*.

According to the regulation, "adverse information" is defined as "any statement or release by the Department **or any principal operating component** made to the news media inviting public attention to an action or a finding by the Department or principal operating component of the Department which may adversely affect persons or organizations identified therein." 45 C.F.R. § 17.1.

> Adverse information **relating to regulatory investigations** of specifically identified persons or organizations or to pending agency trial-type proceedings shall be released **only in limited circumstances** in accordance with the criteria outlined below:
>
> Where the Department **or a principal operating component** determines that there is a **significant risk** that the public health or safety may be impaired or **substantial economic harm** may occur unless the public is notified **immediately**, it may release information to news media as one of the means of notifying the affected public **speedily and accurately**.

45 C.F.R. § 17.4(a). As an operating component of the HHS, it appears the CDC the CDC is obligated to abide by these regulations. If we are misguided in our interpretation of these regulations, please feel to point us in the right direction.

Public Comments by CDC Officials

The CDC has released adverse information in a way that does not comport with HHS guidelines. Specifically, CDC officials have made misleading and unnecessary comments to the media about matters which relate to an ongoing agency investigation. On November 20, 2015, a CDC representative was quoted by a national news outlet as follows:

> The cause of the outbreak hasn't been determined, but it "probably wasn't meat," Matt Wise, a CDC epidemiologist who is leading the investigation, said in an interview. He noted that a "couple of vegetarians" are among those sickened.
>
> "The fact that these outbreaks don't seem to be confined to a geographical region is harmful to the brand," he said. "Chipotle's brand-perception problem has just gone coast to coast."

See **Exhibit B**. These comments were made nearly three weeks into the *E. coli* investigation, and at a time when all affected food was removed from Chipotle restaurants and supply chains. Therefore, there was no impending public health risk which necessitated the statements. Moreover, these comments were not an accurate representation of the status of the investigation. Neither the government agencies, Chipotle, nor any privately retained experts have been able to identify the source of the *E. coli*. As such, it has not been feasible to rule out any one ingredient as the cause of the outbreak. We believe these remarks were unnecessary and not made in a legitimate attempt to avoid a significant risk to public health or safety.

Dimare Fresh, Inc. v. U.S.

It is our understanding that the CDC is relying upon the holding of *Dimare Fresh, Inc. v. U.S.* in its justification of the web updates. However, the issues addressed in *Dimare* are distinguishable from the present situation. *Dimare* is a case that deals with the premature release of information related to tainted tomatoes. By contrast, it is Chipotle's position that the CDC's timing of the initial notification of the outbreak was justified. Chipotle is only concerned with additional web updates made after substantial risk to the public had passed.

Dimare Fresh, Inc. v. U.S. was a 2015 case filed by tomato growers. The tomato growers claimed that a preemptive warning to the public by the FDA negatively and needlessly impacted the growers' sales. The tomato growers made the argument that this warning should be legally characterized as a regulatory taking and, as a result, the tomato growers should be compensated for their losses. In its opinion, the Court acknowledged that the FDA did legally have the authority to regulate, and thus its regulation had the necessary legal effect for a taking. However, the Court was not persuaded that a taking occurred; they felt that the fact that FDA's warning was ultimately proven unnecessary was "academic" to this issue, and that the government cannot be responsible for a taking each time they issue an incorrect statement.

The circumstances in *Dimare* are not analogous to our request to withhold the web updates. First, the FDA was trying to prevent a larger spread of an outbreak **before** the outbreak was contained. Here, while we may not be aware of the cause of this *E.coli* O26 outbreak, the danger has passed because the affected food products are no longer in Chipotle restaurants. Chipotle has provided the FDA and CDC with information related to the specific lots each suspected food item came from and data regarding when those lots were out of the restaurants. Second, Chipotle is not requesting any compensation for damages from the CDC in connection with our request to withhold the web updates. Chipotle is simply asking the CDC to review CDC, HHS, and OMB guidelines to ensure it is in conformance with the same prior to issuing any additional web updates.

Once again, thank you for allowing us to have this discussion. We value the relationship we have established with the CDC. We would implore the CDC to take into consideration the guidelines and regulations discussed above before issuing additional web updates. As always, please do not hesitate to reach out to us with any comments or questions.

Sincerely,

MESSNER REEVES LLP

Bryant "Corky" Messner, Esq.

Attachments x 2

EXHIBIT A

GUIDELINES FOR ENSURING THE QUALITY OF INFORMATION DISSEMINATED TO THE PUBLIC

D. CENTERS FOR DISEASE CONTROL AND PREVENTION AND AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY

CONTENTS

I. AGENCY MISSION

The Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) are two of the operating components of the HHS. CDC has remained at the forefront of public health efforts to prevent and control infectious and chronic diseases, injuries, workplace hazards, disabilities, and environmental and occupational health threats for more than 50 years. CDC is the lead federal agency for protecting the health and safety of people at home and abroad, providing credible information to enhance health decisions, and promoting health through strong partnerships.

CDC seeks to accomplish its mission by working with partners throughout the nation and world to monitor health, detect and investigate health problems, conduct research to enhance prevention, develop and advocate sound public health policies, implement prevention strategies and programs, promote healthy behaviors, foster safe and healthful environments, and provide leadership and training.

CDC has developed and sustained many vital partnerships with public and private entities that improve service to the American people. In FY 2000, the workforce of CDC comprised approximately 8,500 FTE in 170 disciplines with a public health focus. Although CDC's national headquarters is in Atlanta, Georgia, more than 2,000 CDC employees work at other locations nationwide including virtually all States. Approximately 160 are assigned overseas in 45 countries. In addition, CDC is comprised of 12 Centers, Institutes, and Offices (CIOs). These organizational components, listed below, respond individually in their areas of expertise and pool their resources and expertise on cross-cutting issues and specific health threats.

- National Center on Birth Defects and Developmental Disabilities
- National Center for Chronic Disease Prevention and Health Promotion
- National Center for Environmental Health
- National Center for Health Statistics
- National Center for HIV, STD, and TB Prevention
- National Center for Infectious Diseases
- National Center for Injury Prevention and Control
- National Immunization Program
- National Institute for Occupational Safety and Health
- Epidemiology Program Office
- Public Health Practice Program Office
- Office of the Director

ATSDR was established in 1980 by the Comprehensive Environmental Response, Compensation, and Liability Act, also known as Superfund. ATSDR works to prevent exposures to hazardous wastes and to environmental releases of hazardous substances. Working with States and other Federal agencies, ATSDR seeks to prevent exposure and adverse health effects associated with exposure to hazardous substances from waste sites. The agency conducts public health assessments, health studies, surveillance activities and health education training in communities around waste sites or exposed to environmental releases. ATSDR also develops toxicological profiles of hazardous chemicals found at

these sites. The agency has 10 regional offices and an office in Washington, DC, and a staff of about 400 persons.

Although CDC and ATSDR are separate agencies, both strive to protect and improve the health of the American public. The Director of CDC also serves as the Administrator of ATSDR.

Unless otherwise specified, all subsequent references to CDC also include ATSDR and all practices and procedures described in this document apply to both agencies.

II. SCOPE AND APPLICABILITY OF GUIDELINES FOR CDC

CDC will ensure that disseminated information meets the standards of quality set forth in the OMB, HHS and CDC guidelines. It is CDC's policy to ensure and maximize the quality, objectivity, utility, and integrity of information that it disseminates to the public. We strive to provide information that is accurate, reliable, clear, complete, unbiased, and useful. We are committed to integrating the principle of information quality into every phase of information development, including creation, collection, maintenance, and dissemination. CDC guidelines do not apply to the National Center for Health Statistics (NCHS). While NCHS is a component of CDC, NCHS is the nation's principal health statistics agency and as such has separate guidelines.

The pre-dissemination review described in the guidelines only applies to information disseminated on or after October 1, 2002. The administrative mechanism for correction applies to information that the agency disseminates on or after October 1, 2002, regardless of when the agency first disseminated the information.

The guidelines apply to information in all media print, electronic, audiovisual, and oral. They apply to substantive information, such as studies and reports, rather than to information pertaining to basic agency operations. Information that is disseminated at the request of CDC or with specific CDC approval through a contract, a grant, or a cooperative agreement is subject to these guidelines.

Examples are provided below of the types of information that the CDC considers within and outside the scope of the guidelines.

A. Covered Information

- Scientific research papers, books, journal articles, reports, and similar materials, unless they have disclaimers to distinguish the research from CDC views and positions;
- Other official reports, brochures, documents, newsletters, and audiovisual products;
- Oral information, including speeches, interviews, expert opinions only if representing CDC's views, official positions, or policies;

- Statistical information - statistical analyses, aggregated information by programs.

- **Information Not Covered**

- Documents not authored by CDC (either directly or by contract) and not representing official views, including research and science supported by CDC funding;
- Opinions where the presentation makes it clear that what is being offered is personal opinion rather than fact or CDC's views;
- Archival information disseminated by CDC (for example, Internet distribution of published articles);
- Information dissemination limited to government employees or agency contractors or grantees;
- Information intended solely for intra- or inter-agency use or sharing of government information, such as evaluation of a specific public health program to assess the success in achieving its objectives, technical assistance reports, training materials, manuals;
- Information intended to be limited to public filings, subpoenas, or adjudicative processes;
- Press releases that support the announcement or give public notice of information that CDC has disseminated elsewhere.

III. TYPES OF INFORMATION DISSEMINATED BY CDC TO THE PUBLIC

Annually, CDC produces hundreds of publications of various types and provides over 100,000 pages of Web content for access by the public. All publications that carry the CDC logo are considered official publications or releases, and must follow CDC policy and procedures for preparation, review, approval, and distribution (www.cdc.gov/od/foia/policies/clearance.htm).

Examples of the types of information disseminated by CDC to the public are listed below. Some types fit into more than one category and are mentioned in each.

A. Scientific research studies.
CDC encourages professional dissemination of scientific research by employees and those funded by CDC to conduct research. These research studies may be published by CDC, such as the *Morbidity and Mortality Weekly Report* (MMWR) or non-CDC publications including journals, books, chapters, editorials, reviews, proceedings or abstracts. These are usually authored by or co-authored by CDC staff scientists as part of their official duties or may be authored by CDC partners, CDC advisory committees, or working groups convened by CDC.

B. Statistical products
CDC releases data sets and disseminates statistical reports produced by its data collection programs. These include vital statistics, population-based health surveys, and surveys of health care providers.

C. Programmatic and administrative information.
CDC disseminates community health assessments and information in connection with and as a

byproduct of the administration of programs, such as Program-in-Brief documents, At-A-Glance documents, and program brochures.

D. **Authoritative health, medical and human services information aimed at consumers and health and human services professionals.**
CDC publishes the *MMWR* which includes *Recommendations and Reports*. CDC generates Health Alerts, Public Health Advisories, and guidelines for dealing with specific public health threats. CDC also provides the website *Travelers' Health*, which publishes guidelines for international travelers including the "Yellow Book" and official expert opinions. CDC produces and broadcasts science educational materials and training modules, including Public Health Grand Rounds Satellite broadcasts, Web-assisted Audio Conferences for State and Local Health Policymakers, and the Health Training Network Satellite Broadcast.

E. **Public heath surveillance, and epidemiology information.**
CDC publishes the *MMWR Summary of Notifiable Diseases* and *CDC Surveillance Summaries*, and other surveillance summaries on a variety of infectious diseases such as HIV/AIDS and tuberculosis, as well as other non-infectious conditions such as Birth Defects Surveillance, National Oral Health Surveillance, Pediatric Nutrition Surveillance, Pregnancy Nutrition Surveillance, Hazardous Substance Release/Health Effects Database, Flu Bulletin, Influenza Season Reports and Occupational Morbidity and Mortality Surveillance, Adult Blood Lead Epidemiology and Surveillance, Coal Workers X-ray Surveillance Program, National Surveillance System of Pneumoconiosis Mortality, National Traumatic Occupational Fatalities Surveillance System. In addition CDC publishes outbreak investigations or other items reported in the MMWR that are not authoritative or urgent. ATSDR disseminates information products including Public Health Assessments, Public Health Consultations, Fact Sheets, health study reports, Toxicological Profiles, Case Studies in Environmental Medicine, and Hazardous Substances and Public Health (newsletter).

IV. TYPES OF DISSEMINATION METHODS

CDC disseminates information through a wide range of methods, often using more than one medium for the same information.

A. **Print**
including publications in peer-reviewed literature, published reports, periodicals, brochures, books, and correspondence;

B. **Electronic**
such as the CDC Website, CD -ROM, Listserv, e-mail, automated voice and fax systems, hotlines and clearinghouses;

C. **Audiovisual**
broadcast scripts, audio or videotapes, and videocasting. CDC's Public Health Training Network makes satellite broadcasts and Webcasts available nationally.

D. **Oral**
formal speeches, oral presentations, and interviews, or commentaries for publication or broadcast.

V. AGENCY QUALITY ASSURANCE POLICIES, STANDARDS AND PROCESSES FOR ENSURING THE QUALITY OF INFORMATION DISSEMINATION TO THE PUBLIC.

A. Overview

CDC's policies and procedures are designed to ensure and maximize the quality of its information products with regard to their utility, objectivity, and integrity. The agency's quality assurance process begins at the inception of the information development process. CDC has guidelines to address the general principles concerning the responsibilities of the CDC staff in the collection and recording of data, publication practices, authorship determination, peer review, confidentiality of information, collaborations, and human subjects research. Authorship issues and review and clearance procedures are set forth in the "Authorship of CDC Publications and the Clearance Procedures for Scientific and Technical Documents" (www.cdc.gov/od/foia/policies/clearance.htm).

CDC reviews the quality (including the objectivity, utility, and integrity) of information before it is disseminated and treats information quality as integral to every step of the development of information, including its creation, collection, maintenance and dissemination. Further, CDC is committed to demonstrating in its Paperwork Reduction Act clearance packages that each draft information collection will result in information that will be collected, maintained, and used in a way that is consistent with OMB, HHS and CDC information quality guidelines. The individual CIO Associate Directors for Science (ADS) or designee are responsible for assuring the quality of information disseminated by CDC and that the quality assurance methods and procedures described in Overview of Quality Assurance Policies and Practices in HHS are met. To meet the standards for external merit review of research and scientific studies and intramural research programs, CDC policy is to peer review extramural research and intramural research studies and programs.

The CIO ADS or designee are responsible for clearance of documents originating in that CIO before dissemination and for ensuring that the necessary clearances are obtained and that written material distributed is appropriate and consistent with HHS policy. While each CIO can determine preparation, review and approval procedures, all must meet standards provided by the ADS, CDC and those provided in the HHS Part I Overview D.4.d.

- **Utility** CDC addresses utility, a measure of the usefulness of information products to its intended users, by staying informed of user needs through information product research and user needs assessment, user feedback, consultation with advisory committees, and conference participation.
- **Objectivity** CDC provides assurance that information is accurate, reliable, and unbiased. Objectivity is achieved through existing review and clearance procedures and, in many cases, the peer review of disseminated information.

- **Integrity** CDC assures the integrity of its data and information products through the enforcement of rigorous controls that protect against unauthorized access, revision, or corruption. Some of the controls used at CDC include access control, user authentication, encryption, access monitoring, provision of unalterable electronic content, and audit trails.

- **CDC Information Review and Approval Policies and Procedures by Type of Information**

a. Health and Public Health Information

1. Scientific research studies

CDC encourages professional dissemination of scientific research and other information by its employees. Publications or presentations by CDC employees are expected to meet high standards of quality, make a substantial contribution to the field, and contain sufficient information for the informed audience to assess its validity. Publication of scientific information by individual employees must undergo a formal review and clearance process by the CIO ADS or designee before dissemination. This review includes the evaluation of data collection measures for completeness, accuracy and timeliness, data management and analysis, clarity and accuracy of presentation, and validity of interpretation of findings.

Oral presentations undergo appropriate supervisory review. Laboratory data are reviewed to assure that good laboratory data practice was followed for sampling, methodology, instrumentation and analysis.

Intramural research programs will be subject to review and monitoring by external, objective peer review through an advisory committee or board of scientific counselors. Scientific research studies submitted to journals are subject to peer review of methods and findings by the journal prior to publication. ATSDR has a mandated policy for external peer review of all intramural and extramural research study protocols and findings prior to public dissemination.

2. Authoritative health, medical and human services information aimed at consumers and health and human services professionals

CDC disseminates authoritative health and medical information routinely as part of its mission. As an example, articles or reports for publication in the MMWR are subject to routine CDC review and approval procedures in the originating CIO. Because information disseminated in the MMWR often has impact on the practice of public health, the CDC ADS must also review and approve it. Health Alerts related to bioterrorism that are disseminated by CDC are also reviewed and approved at the CDC ADS level prior to release.

3. Public heath surveillance and epidemiology information

CDC often obtains surveillance information from third parties, such as States, grantees, or community-based organizations. Reliance on third parties places limits on CDC's quality assurance, although the accuracy, completeness and timeliness of the information are

subject to sample audits, site visits, and an evaluation for completeness and consistency with trends and external controls. The *MMWR Summary of Notifiable Diseases*, for example, depends on data reported from States. CDC conducts audits and checks for consistency for trends before reporting these data. ATSDR produces Toxicological Profiles for hazardous substances found at National Priorities List sites as well as other documents that undergo public comment periods before being finalized and distributed. The Toxicological Profiles and other ATSDR documents are first produced as drafts and are then subject to public comments following announcement in the Federal Register and using other means. Only after considering the comments, the profiles and documents are finalized and then distributed to the public.

ATSDR has a government to government policy on Tribal Nations that specifies how the agency works with and respects Tribal rights, sovereignty, and culture. Data or information collected from American Indian/Alaska Native communities requires approval from the Tribal government and direct involvement in the research or study from concept to completion. The Tribe reserves the right to review and critique the design and findings. Issues of release and ownership of data, information or other products must be agreed to by the Tribal government. Close collaboration and involvement of the Tribe is essential to ensure quality, utility, objectivity and integrity of information prior to being disseminated.

b. **Statistical products**

CDC routinely employs a number of widely accepted methods and procedures for ensuring quality, including independent assessments of statistical methodologies, peer reviews, and observance of professional standards. To insure the utility of CDC statistical and analytic information products, CDC conducts independent research and consults experts in areas such as data collection, data analysis and a variety of substantive topics and areas. Additionally, CDC maintains ongoing contact with users, and participates in conferences, and workshops in order to objectively assess and identify the current and future data needs of CDC's constituents. Further, CDC employs a wide variety of dissemination mechanisms to make its statistical and analytic information products widely available and broadly accessible.

To assure that statistical and analytic information products are accurate, reliable, and unbiased, CDC obtains these data through generally accepted statistical theory and practice. Dissemination of data also follows generally recognized guidelines in terms of defining acceptable standards regarding minimum response rates, maximum standard errors, cell size suppression, quality of coding and other processing operations. CDC also maintains staff expertise in areas such as concept development, survey planning and design, data collection, data processing and editing, data analysis, evaluation procedures, and methods of data dissemination.

All CDC statistical and analytic information products undergo a formal clearance process before dissemination. Publications and reports, whether in electronic or paper form, are reviewed by a CIO ADS or designee. These reviews cover the clarity of descriptive text, the appropriateness of the methodology, the soundness of the analysis, the adherence to confidentiality and disclosure avoidance restrictions, the readability of tabular and graphic presentations of data. Finally, all

products undergo editorial review, (e.g., formatting, proofreading, spell checks, proper punctuation). Oral presentations undergo appropriate supervisory review. The CIO ADS or designee may also review for programmatic and policy implications on behalf of and in consultation with other division or senior staff. In addition, all public-use tapes are reviewed by the CIO ADS or designee for accuracy and appropriate confidentiality protections.

CDC statistical and analytic information products are derived using generally acceptable statistical practices and methodologies which are clearly documented and available to the public. These procedures enable responsible statisticians and analysts outside of CDC to replicate CDC's statistical methods and obtain results consistent with those obtained by CDC.

VI. AGENCY ADMINISTRATIVE COMPLAINT PROCEDURES

CDC has developed administrative mechanisms to allow affected persons to seek and obtain correction of disseminated information that does not comply with OMB, HHS and CDC guidelines.

CDC will establish a Website to advise information consumers of the agency's information quality guidelines, the process to submit a complaint, information needed by the complainant, and a description of the complaint adjudication process. CDC will centralize the initial receipt, logging, and tracking of all complaints received under this provision in the Management Analysis and Services Office (MASO), Office of Program Services. Complaints will be forwarded to the office that has subject matter responsibility for the information product in question.

A. Responsibility of the Complainant

To seek a correction of information disseminated by the agency, individuals must follow the procedures described below:

1. complaints or requests for review and correction of information must be in written (hard copy or electronic) form;
2. requests shall be sent to CDC by mail at CDC/ATSDR, Attn: MASO, MS-E11, 1600 Clifton Road, N.E.; Atlanta, GA 30333 or by e-mail at: InfoQuality@cdc.gov; and
3. requests shall state that an information quality request for correction is being submitted.

The complaint must contain:

4. a detailed description of the specific information that needs to be corrected including where the information is located, i.e. the publication title, date, and publication number, if any, or the Website and Web page address (url), or the speech title, presenter, date and place of delivery;

5. the specific reasons for believing the information does not comply with OMB, HHS or CDC guidelines and is in error and supporting documentation, if any;
6. the specific recommendations for correcting the information;
7. a description of how the person submitting the complaint is affected by the information error; and
8. the name, mailing address, telephone number, e-mail address, and organizational affiliation, if any, of the individual making the complaint.

Complainants should be aware that they bear the 'burden of proof' with respect to the necessity for correction as well as with respect to the type of correction they seek.

B. CDC/ATSDR Responsibility

CDC will respond to all requests for correction within 60 calendar days of receipt. If the request requires more than 60 calendar days to resolve, the requestor will be informed that more time is required, notified of the reason why, and provided an estimated decision date. Based on a review of the information provided, the agency will determine whether a correction is warranted and, if so, what action to take. CDC will respond to the requestor by letter or e-mail, explaining the findings of the review and the actions that the agency will take, if any. The response will consider the nature and timeliness of the information involved and such factors as the significance of the correction on the use of the information and the magnitude of the correction. The response will describe how the complainant may request reconsideration of the CDC decision.

C. Appeals

If the individual submitting the complaint does not agree with CDC's decision (including the corrective action, if any), the complainant may send a written hard copy or electronic request for reconsideration within 30 days of receipt of the agency's decision. The appeal must state the reasons why the agency response is insufficient or inadequate. Complainants must attach a copy of their original request and the agency's response to it. Clearly mark the appeal with the words, "Information Quality Appeal," and send the appeal by mail to CDC/ATSDR, Attn: MASO, MS-E11; 1600 Clifton Road, N.E., Atlanta, GA 30333 or by e-mail to InfoQuality@cdc.gov.

The agency will respond to all requests for appeals within 60 calendar days of receipt. If the request requires more than 60 calendar days to resolve, the agency will inform the complainant that more time is required and indicate the reason why and an estimated decision date.

The agency official who resolved the original complaint will not have responsibility for the appeal. MASO will direct all appeals to an appropriate CDC official in the Office of the Director based on the nature of the information product and complaint.

VII. INFLUENTIAL SCIENTIFIC, FINANCIAL AND STATISTICAL INFORMATION

CDC considers the information disseminated in the *MMWR Recommendations and Reports*, the Hazardous Substance Release/Health Effects Database, Toxicological Profiles, ATSDR Public Health Assessments, and Federal Register publications related to science as influential scientific information.

RISK ASSESSMENT

Some of the influential information that we disseminate is based on an analysis of the risks to the public of certain actions or exposures to hazardous substances. For purposes of this guidance, we are defining risk as the likelihood that injury or damage is or can be caused by a substance, technology, or activity. We use risk analysis (the integration of risk assessment with risk management and risk communication) as a tool to enhance the scientific basis for all of our regulatory decisions.

The OMB Guidelines provide special considerations that must be taken into account in certain risk assessments, those that provide the basis for the dissemination of influential information. The guidelines state that "With regard to analysis of risks to human health, safety, and the environment maintained or disseminated by the agencies, agencies shall either adopt or adapt the quality principles applied by Congress to risk information used and disseminated pursuant to the Safe Drinking Water Act Amendments of 1996 (SDWA) (42 U.S.C. 300g-1(b)(3)(A) and (B))."

The SDWA risk assessment principles are as follows:

1. To the degree that the agency action is based on science, the agency shall use
    a. the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices
    b. data collected by accepted methods (if reliability of the method and the nature of the decision justify use of the data)
2. In the dissemination of public information about risks, the agency shall ensure that the presentation of information about risk effects is comprehensive, informative, and understandable.
3. In a document made available to the public in support of a regulation, the agency shall specify, to the extent practicable
    a. Each population addressed by any estimate of applicable risk effects
    b. The expected risk or central estimate of risk for the specific populations affected
    c. Each appropriate upper-bound or lower-bound estimate of risk
    d. Each significant uncertainty identified in the process of the assessment of risk effects and the studies that would assist in resolving the uncertainty and
    e. Peer-reviewed studies known to the agency that support, are directly relevant to, or fail to support any estimate of risk effects and the methodology used to reconcile the inconsistencies in the scientific data

Many of our actions are based on scientific experts' judgments using available data, are essentially qualitative and do not lend themselves to the types of quantitative risk assessments contemplated by the SDWA principles. As a result, we have adapted the general principles for risk assessments from the SDWA to fit these situations.

1. The agency will use
    a. the best available science and supporting studies conducted in accordance with sound and objective scientific practices, including peer-reviewed science and supporting studies when available
    b. data collected by accepted methods (if reliability of the method and the nature of the decision justify use of the data)
2. In the dissemination of public information about risks, the agency will ensure that the presentation of information about risk effects is comprehensive, informative, and understandable.

In situations where a quantitative risk assessment is conducted, we generally follow basic risk assessment principles in the NAS paradigm of 1983. Our needs for quantitative risk assessments range over a wide variety of hazards including physical hazards encountered during exposure to toxic substances and antimicrobial resistance to antibiotic therapy. Thus, we also ascribe to the statement from NAS when it revisited the risk assessment process in 1994 (*Science and Judgment in Risk Assessment*, NAS 1994): "Risk assessment is not a single process, but a systematic approach to organizing and analyzing scientific knowledge and information." In each of the areas we regulate, we apply risk assessment practices to the specific task that are widely accepted among relevant domestic and international public health agencies.

For quantitative risk assessments in support of the dissemination of influential information, CDC intends to apply the following principles:

1. The agency will use
    a. the best available science and supporting studies conducted in accordance with sound and objective scientific practices, including peer-reviewed science and supporting studies when available.
    b. data collected by accepted methods (if reliability of the method and the nature of the decision justifies use of the data).
2. In the dissemination of public information about health risks, the agency shall ensure that the presentation of information is comprehensive, informative, and understandable, within the context of its intended purpose.
3. In a document made available to the public, the agency shall specify, to the extent practicable-
    a. Each population addressed by any estimate of applicable effects;
    b. The expected or central estimate of risk for the specific populations affected;
    c. Each appropriate upper-bound and/or lower-bound risk estimates;
    d. Data gaps and other significant uncertainties identified in the process of the risk assessment and the studies that would assist in reducing the uncertaintaies; and

e. Additional studies not used in the risk assessment that support or fail to support the findings of the assessment and the rationale of why they were not used.

VIII. SPECIAL CONSIDERATIONS FOR AGENCY DISSEMINATION

Special consideration also applies to information products that are urgent in nature and because of the potential risk to human health and safety, certain information products may be disseminated in an expedited manner without having fully complied with all normal quality guidelines; however, basic quality principles and processes will still apply and be followed.

EXHIBIT B

BloombergBusiness

An E. coli outbreak linked to Chipotle Mexican Grill Inc. has spread to six states, including California and New York, underscoring that the food-poisoning crisis isn't over for the restaurant operator.

QUICKTAKE
Food Safety

The evidence suggests that an ingredient or "common meal item" served by Chipotle in several states was the source of the outbreak, the Centers for Disease Control and Prevention said in a statement on Friday. A total of 45 people were infected, including two in California, two in Minnesota, one in New York and one in Ohio, the CDC said. Of those people, 43 said they had eaten at a Chipotle.

The cause of the outbreak hasn't been determined, but it "probably wasn't meat," Matt Wise, a CDC epidemiologist who is leading the investigation, said in an interview. He noted that a "couple of vegetarians" are among those sickened.

Chipotle, which operates about 1,900 units, appeared to have limited the damage from the outbreak when it announced last week that it was reopening 43 restaurants that had been closed for cleaning in Washington and Oregon. But now that the E. coli probe has expanded, it "has the potential to become a longer-term problem than the company would like," said Asit Sharma, an analyst at the Motley Fool.

"The fact that these outbreaks don't seem to be confined to a geographical region is harmful to the brand," he said. "Chipotle's brand-perception problem has just gone coast to coast."

Shares Plummet

The company's shares tumbled 12 percent to close at $536.19 in New York, marking the worst drop in more than three years. The stock was already down 11 percent this year before Friday, hurt by concerns about slowing growth.

The E. coli probe had previously focused on Oregon and Washington, where dozens of people got sick after eating at Chipotle restaurants. The Denver-based company shuttered locations there for more than a week as authorities investigated the E. coli outbreak. It also hired safety consultants, sanitized the restaurants and threw out unused food. The restaurants reopened about two weeks ago.

On Nov. 17, the CDC said one person in Minnesota also got sick from an E. coli strain that had the same "DNA fingerprint" as the cases in Oregon and Washington. But that person didn't eat at Chipotle in the week before getting ill, the agency said.

'Aggressive Steps'

"The source of the problem appears to have been contained during a period in late October," the company said Friday in a statement. "In response to this incident, Chipotle has taken aggressive steps to make sure its restaurants are as safe as possible. There have been no reported new cases in Washington or Oregon since Chipotle put its remediation plan into effect."

The E. coli scare follows a salmonella outbreak in Minnesota in September, when Chipotle restaurants were linked to dozens of infections. In that case, authorities identified tainted tomatoes as the source. One Chipotle location in California, meanwhile, saw about 80 customers sickened by an outbreak of norovirus over the summer.

• markets • Chipotle Mexican Grill Inc • California • New York