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**MONTANA EIGHTEENTH JUDICIAL DISTRICT COURT, GALLATIN COUNTY**

<p>RICHARD WEST, individually and on behalf of L.W., a minor,</p> <p style="text-align: center;">Plaintiff,</p> <p style="text-align: center;">vs.</p> <p>MCDONALD’S CORPORATION, a Delaware corporation, SAPPHIRE RESTAURANTS, INC. d/b/a McDonald’s,</p> <p style="text-align: center;">Defendant(s).</p>	<p style="text-align: center;"><b>Cause No.</b></p> <p style="text-align: center;"><b>COMPLAINT AND DEMAND FOR JURY TRIAL</b></p>
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**COMES NOW**, Plaintiff RICHARD WEST individually and on behalf of L.W., a minor (“Plaintiff”), through her attorneys at Bliven Law Firm, P.C., and Marler Clark, Inc., PS (*pro hac vice* forthcoming) and files this Complaint and Demand for Jury Trial, and complains and alleges as follows upon information and belief:

## **PARTIES, JURISDICTION, AND VENUE**

1. Jurisdiction for this cause lies within the State of Montana, in that the injuries which are the subject of this Complaint occurred within the State of Montana.
2. Venue is proper in the above Court in that the events out of which this claim arose occurred in Gallatin County, Montana.
3. At all material times, L.W., a minor, and her father, Richard West, were residents of Townsend, Broadwater County, Montana.
4. At all material times, Defendant McDonald's Corporation, (hereinafter "McDonald's" or "Defendant") was a foreign corporation incorporated under the laws of Delaware and headquartered in Chicago, Illinois at 110 N. Carpenter St. Chicago, IL 60607. At all times relevant hereto, the defendant franchised and exercised operational control over the McDonald's restaurant located at 207 Jefferson Street, Belgrade, MT 59714 and was authorized to do and regularly did business in the State of Montana.
5. At all material times, Defendant Sapphire Restaurants, Inc. (hereinafter "Sapphire" or "Defendant") was a corporation incorporated under the laws of the State of Montana, and headquartered at 1227 N 14<sup>th</sup> Ave, Ste 2, Bozeman, MT 59718. At all times relevant hereto, Sapphire was the franchisee operating the McDonald's restaurant located at 207 Jefferson Street, Belgrade, MT 59714 and was authorized to do and regularly did business in the State of Montana.

## **FACTS COMMON TO ALL COUNTS**

6. As of October 30, 2024, 90 individuals, 27 of whom were hospitalized and one who died, have been identified as confirmed cases of an outbreak of *E. coli* O157:H7 among 13 states including Montana. The outbreak is ongoing.

7. According to the CDC, all interviewed individuals purchased and consumed food from McDonalds restaurants, and most reported having eaten a Quarter-Pounder hamburger.
8. An internal investigation by McDonalds, and another conducted by the CDC has identified slivered yellow onions as the likely vehicle for the outbreak.
9. McDonald's removed slivered yellow onions and beef patties used in the Quarter-Pounder from stores in the affected states.
10. *E. coli* is an archetypal commensal bacterial species that lives in mammalian intestines. *E. coli* O157:H7 is one of thousands of serotypes *Escherichia coli*.<sup>1</sup> The combination of letters and numbers in the name of the *E. coli* O157:H7 refers to the specific antigens (proteins which provoke an antibody response) found on the body and tail or flagellum<sup>2</sup> respectively and distinguish it from other types of *E. coli*.<sup>3</sup> Most serotypes of *E. coli* are harmless and live as normal flora in the intestines of healthy humans and animals.<sup>4</sup> The *E. coli* bacterium is among the most extensively studied microorganism.<sup>5</sup> The testing done to distinguish *E. coli* O157:H7 from its other *E. coli* counterparts is called serotyping.<sup>6</sup> Pulsed-field gel electrophoresis (PFGE),<sup>7</sup> sometimes also referred to as genetic fingerprinting, is used to

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<sup>1</sup> *E. coli* bacteria were discovered in the human colon in 1885 by German bacteriologist Theodor Escherich. Feng, Peter, Stephen D. Weagant, Michael A. Grant, Enumeration of *Escherichia coli* and the Coliform Bacteria, in BACTERIOLOGICAL ANALYTICAL MANUAL (8<sup>th</sup> Ed. 2002), <http://www.cfsan.fda.gov/~ebam/bam-4.html>. Dr. Escherich also showed that certain strains of the bacteria were responsible for infant diarrhea and gastroenteritis, an important public health discovery. *Id.* Although the bacteria were initially called Bacterium coli, the name was later changed to *Escherichia coli* to honor its discoverer. *Id.*

<sup>2</sup> Not all *E. coli* are motile. For example, *E. coli* O157:H7 which lack flagella are thus *E. coli* O157:NM for non-motile.

<sup>3</sup> CDC, *Escherichia coli* O157:H7, General Information, Frequently Asked Questions: What is *Escherichia coli* O157:H7?, [http://www.cdc.gov/ncidod/dbmd/diseaseinfo/escherichiacoli\\_g.htm](http://www.cdc.gov/ncidod/dbmd/diseaseinfo/escherichiacoli_g.htm).

<sup>4</sup> Marion Nestle, Safe Food: Bacteria, Biotechnology, and Bioterrorism, 40-41 (1<sup>st</sup> Pub. Ed. 2004).

<sup>5</sup> James M. Jay, MODERN FOOD MICROBIOLOGY at 21 (6<sup>th</sup> ed. 2000). (“This is clearly the most widely studied genus of all bacteria.”)

<sup>6</sup> Beth B. Bell, MD, MPH, *et al.* A Multistate Outbreak of *Escherichia coli* O157:H7-Associated Bloody Diarrhea and Hemolytic Uremic Syndrome from Hamburgers: The Washington Experience, 272 JAMA (No. 17) 1349, 1350 (Nov. 2, 1994) (describing the multiple step testing process used to confirm, during a 1993 outbreak, that the implicated bacteria were *E. coli* O157:H7).

<sup>7</sup> Jay, *supra* note 5, at 220-21 (describing in brief the PFGE testing process).

compare *E. coli* O157:H7 isolates to determine if the strains are distinguishable.<sup>8</sup> A technique called multilocus variable number of tandem repeats analysis (MLVA) is used to determine precise classification when it is difficult to differentiate between isolates with indistinguishable or very similar PFGE patterns.<sup>9</sup>

11. *E. coli* O157:H7 was first recognized as a pathogen in 1982 during an investigation into an outbreak of hemorrhagic colitis<sup>10</sup> associated with consumption of hamburgers from a fast food chain restaurant.<sup>11</sup> Retrospective examination of more than three thousand *E. coli* cultures obtained between 1973 and 1982 found only one (1) isolation with serotype O157:H7, and that was a case in 1975.<sup>12</sup> In the ten (10) years that followed there were approximately thirty (30) outbreaks recorded in the United States.<sup>13</sup> This number is likely misleading, however, because *E. coli* O157:H7 infections did not become a reportable disease in any state until 1987 when Washington became the first state to mandate its

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<sup>8</sup> *Id.* Through PFGE testing, isolates obtained from the stool cultures of probable outbreak cases can be compared to the genetic fingerprint of the outbreak strain, confirming that the person was in fact part of the outbreak. Bell, *supra* note 6, at 1351-52. Because PFGE testing soon proved to be such a powerful outbreak investigation tool, PulseNet, a national database of PFGE test results was created. Bala Swaminathan, *et al.* PulseNet: The Molecular Subtyping Network for Foodborne Bacterial Disease Surveillance, United States, 7 *Emerging Infect. Dis.* (No. 3) 382, 382-89 (May-June 2001) (recounting the history of PulseNet and its effectiveness in outbreak investigation).

<sup>9</sup> Konno T. *et al.* Application of a multilocus variable number of tandem repeats analysis to regional outbreak surveillance of Enterohemorrhagic *Escherichia coli* O157:H7 infections. *Jpn J Infect Dis.* 2011 Jan; 64(1): 63-5.

<sup>10</sup> “[A] type of gastroenteritis in which certain strains of the bacterium *Escherichia coli* (*E. coli*) infect the large intestine and produce a toxin that causes bloody diarrhea and other serious complications.” The Merck Manual of Medical Information, 2<sup>nd</sup> Home Ed. Online, <http://www.merck.com/mmhe/sec09/ch122/ch122b.html>.

<sup>11</sup> L. Riley, *et al.* Hemorrhagic Colitis Associated with a Rare *Escherichia coli* Serotype, 308 *New Eng. J. Med.* 681, 684-85 (1983) (describing investigation of two outbreaks affecting at least 47 people in Oregon and Michigan both linked to apparently undercooked ground beef). Chinyu Su, MD & Lawrence J. Brandt, MD, *Escherichia coli* O157:H7 Infection in Humans, 123 *Annals Intern. Med.* (Issue 9), 698-707 (describing the epidemiology of the bacteria, including an account of its initial discovery).

<sup>12</sup> Riley, *supra* note 11 at 684. See also Patricia M. Griffin & Robert V. Tauxe, The Epidemiology of Infections Caused by *Escherichia coli* O157:H7, Other Enterohemorrhagic *E. coli*, and the Associated Hemolytic Uremic Syndrome, 13 *Epidemiologic Reviews* 60, 73 (1991).

<sup>13</sup> Peter Feng, *Escherichia coli* Serotype O157:H7: Novel Vehicles of Infection and Emergence of Phenotypic Variants, 1 *Emerging Infect. Dis.* (No. 2), 47, 47 (April-June 1995) (noting that, despite these earlier outbreaks, the bacteria did not receive any considerable attention until ten years later when an outbreak occurred 1993 that involved four deaths and over 700 persons infected).

reporting to public health authorities.<sup>14</sup> As a result, only the most geographically concentrated outbreak would have garnered enough notice to prompt further investigation.<sup>15</sup>

12. *E. coli* O157:H7's ability to induce injury in humans is a result of its ability to produce numerous virulence factors, most notably Shiga-like toxins.<sup>16</sup> Shiga toxin (Stx) has multiple variants (e.g. Stx1, Stx2, Stx2c), and acts like the plant toxin ricin by inhibiting protein synthesis in endothelial and other cells.<sup>17</sup> Shiga toxin is one of the most potent toxins known.<sup>18</sup> In addition to Shiga toxins, *E. coli* O157:H7 produces numerous other putative virulence factors including proteins, which aid in the attachment and colonization of the bacteria in the intestinal wall and which can lyse red blood cells and liberate iron to help support *E. coli* metabolism.<sup>19</sup>
13. *E. coli* O157:H7 evolved from enteropathogenic *E. coli* serotype O55:H7, a cause of non-bloody diarrhea, through the sequential acquisition of phage-encoded Stx2, a large

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<sup>14</sup> William E. Keene, *et al.* A Swimming-Associated Outbreak of Hemorrhagic Colitis Caused by *Escherichia coli* O157:H7 and Shigella Sonnei, 331 New Eng. J. Med. 579 (Sept. 1, 1994). *See also* Stephen M. Ostroff, MD, John M. Kobayashi, MD, MPH, and Jay H. Lewis, Infections with *Escherichia coli* O157:H7 in Washington State: The First Year of Statewide Disease Surveillance, 262 JAMA (No. 3) 355, 355 (July 21, 1989). (“It was anticipated the reporting requirement would stimulate practitioners and laboratories to screen for the organism.”)

<sup>15</sup> *See* Keene, *supra* note 14 at 583. (“With cases scattered over four counties, the outbreak would probably have gone unnoticed had the cases not been routinely reported to public health agencies and investigated by them.”) With improved surveillance, mandatory reporting in 48 states, and the broad recognition by public health officials that *E. coli* O157:H7 was an important and threatening pathogen, there were a total of 350 reported outbreaks from 1982-2002. Josef M. Rangel, et al. Epidemiology of *Escherichia coli* O157:H7 Outbreaks, United States, 1982-2002, 11 Emerging Infect. Dis. (No. 4) 603, 604 (April 2005).

<sup>16</sup> Griffin & Tauxe, *supra* note 12, at 61-62 (noting that the nomenclature came about because of the resemblance to toxins produced by Shigella dysenteries).

<sup>17</sup> Sanding K, Pathways followed by ricin and Shiga toxin into cells, Histochemistry and Cell Biology, vol. 117, no. 2:131-141 (2002). Endothelial cells line the interior surface of blood vessels. They are known to be extremely sensitive to *E. coli* O157:H7, which is cytotoxicogenic to these cells making them a primary target during STEC infections.

<sup>18</sup> Johannes L, Shiga toxins—from cell biology to biomedical applications. Nat Rev Microbiol 8, 105-116 (February 2010). Suh JK, et al. Shiga Toxin Attacks Bacterial Ribosomes as Effectively as Eucaryotic Ribosomes, Biochemistry, 37 (26); 9394–9398 (1998).

<sup>19</sup> Welinder-Olsson C, Kaijser B. Enterohemorrhagic *Escherichia coli* (EHEC). Scand J. Infect Dis. 37(6-7): 405-16 (2005). *See also* USDA Food Safety Research Information Office *E. coli* O157:H7 Technical Fact Sheet: Role of 60-Megadalton Plasmid (p0157) and Potential Virulence Factors, [http://fsrio.nal.usda.gov/document\\_fsheetsheet.php?product\\_id=225](http://fsrio.nal.usda.gov/document_fsheetsheet.php?product_id=225).

virulence plasmid, and additional chromosomal mutations.<sup>20</sup> The rate of genetic mutation of *E. coli* O157:H7 indicates that the common ancestor of current *E. coli* O157:H7 clades<sup>21</sup> likely existed some 20,000 years ago.<sup>22</sup> *E. coli* O157:H7 is a relentlessly evolving organism,<sup>23</sup> constantly mutating and acquiring new characteristics, including virulence factors that make the emergence of more dangerous variants a constant threat.<sup>24</sup> The CDC has emphasized the prospect of emerging pathogens as a significant public health threat for some time.<sup>25</sup>

14. Although foods of a bovine origin are the most common cause of both outbreaks and sporadic cases of *E. coli* O157:H7 infections<sup>26</sup>, outbreak of illnesses have been linked to a wide variety of food items. For example, produce has, since at least 1991, been the source of substantial numbers of outbreak-related *E. coli* O157:H7 infections.<sup>27</sup> Other unusual vehicles for *E. coli* O157:H7 outbreaks have included unpasteurized juices, yogurt, dried salami, mayonnaise, raw milk, game meats, sprouts, and raw cookie dough.<sup>28</sup>

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<sup>20</sup> Kaper JB and Karmali MA. The Continuing Evolution of a Bacterial Pathogen. PNAS vol. 105 no. 12 4535-4536 (March 2008). Wick LM, *et al.* Evolution of genomic content in the stepwise emergence of *Escherichia coli* O157:H7. J Bacteriol 187:1783–1791(2005).

<sup>21</sup> A group of biological taxa (as species) that includes all descendants of one common ancestor.

<sup>22</sup> Zhang W, *et al.* Probing genomic diversity and evolution of *Escherichia coli* O157 by single nucleotide polymorphisms. Genome Res 16:757–767 (2006).

<sup>23</sup> Robins-Browne RM. The relentless evolution of pathogenic *Escherichia coli*. Clin Infect Dis. 41:793–794 (2005).

<sup>24</sup> Manning SD, *et al.* Variation in virulence among clades of *Escherichia coli* O157:H7 associated with disease outbreaks. PNAS vol. 105 no. 12 4868-4873 (2008). (“These results support the hypothesis that the clade 8 lineage has recently acquired novel factors that contribute to enhanced virulence. Evolutionary changes in the clade 8 subpopulation could explain its emergence in several recent foodborne outbreaks; however, it is not clear why this virulent subpopulation is increasing in prevalence.”)

<sup>25</sup> Robert A. Tauxe, Emerging Foodborne Diseases: An Evolving Public Health Challenge, 3 Emerging Infect. Dis. (No. 4) 425, 427 (Oct.-Dec. 1997). (“After 15 years of research, we know a great deal about infections with *E. coli* O157:H7, but we still do not know how best to treat the infection, nor how the cattle (the principal source of infection for humans) themselves become infected.”)

<sup>26</sup> CDC, Multistate Outbreak of *Escherichia coli* O157:H7 Infections Associated with Eating Ground Beef—United States, June-July 2002, 51 MMWR 637, 638 (2002) reprinted in 288 JAMA (No. 6) 690 (Aug. 14, 2002).

<sup>27</sup> Rangel, *supra* note 15, at 605.

<sup>28</sup> Feng, *supra* note 13, at 49. See also USDA Bad Bug Book, *Escherichia coli* O157:H7, <http://www.fda.gov/food/foodsafety/foodborneillness/foodborneillnessfoodbornepathogensnaturaltoxins/badbugbook/ucm071284.htm>.

15. According to a recent study, an estimated 93,094 illnesses are due to domestically acquired *E. coli* O157:H7 each year in the United States.<sup>29</sup> Estimates of foodborne acquired O157:H7 cases result in 2,138 hospitalizations and 20 deaths annually.<sup>30</sup> The colitis caused by *E. coli* O157:H7 is characterized by severe abdominal cramps, diarrhea that typically turns bloody within twenty-four (24) hours, and sometimes fevers.<sup>31</sup> The incubation period—which is to say the time from exposure to the onset of symptoms—in outbreaks is usually reported as three (3) to four (4) days, but may be as short as one (1) day or as long as ten (10) days.<sup>32</sup> Infection can occur in people of all ages but is most common in children.<sup>33</sup> The duration of an uncomplicated illness can range from one (1) to twelve (12) days.<sup>34</sup> In reported outbreaks, the rate of death is 0-2%, with rates running as high as 16-35% in outbreaks involving the elderly, like those that have occurred at nursing homes.<sup>35</sup>
16. What makes *E. coli* O157:H7 remarkably dangerous is its very low infectious dose,<sup>36</sup> and how relatively difficult it is to kill these bacteria.<sup>37</sup> Unlike *Salmonella*, for example, which usually requires something approximating an “egregious food handling error, *E. coli* O157:H7 in ground beef that is only slightly undercooked can result in infection,”<sup>38</sup> as few

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<sup>29</sup> Scallan E, *et al.* Foodborne illness acquired in the United States –major pathogens, *Emerging Infect. Dis.* Jan. (2011), <http://www.cdc.gov/EID/content/17/1/7.htm>.

<sup>30</sup> *Id.*, Table 3.

<sup>31</sup> Griffin & Tauxe, *supra* note 12, at 63.

<sup>32</sup> Centers for Disease Control, Division of Foodborne, Bacterial and Mycotic Diseases, *Escherichia coli* general information, [http://www.cdc.gov/nczved/dfbmd/disease\\_listing/stec\\_gi.html](http://www.cdc.gov/nczved/dfbmd/disease_listing/stec_gi.html). *See also* PROCEDURES TO INVESTIGATE FOODBORNE ILLNESS, 107 (IAFP 5<sup>th</sup> Ed. 1999) (identifying incubation period for *E. coli* O157:H7 as “1 to 10 days, typically 2 to 5”).

<sup>33</sup> Su & Brandt, *supra* note 11 (“the young are most often affected”).

<sup>34</sup> Tauxe, *supra* note 25, at 1152.

<sup>35</sup> *Id.*

<sup>36</sup> Griffin & Tauxe, *supra* note 12, at 72. (“The general patterns of transmission in these outbreaks suggest that the infectious dose is low.”)

<sup>37</sup> V.K. Juneja, O.P. Snyder, A.C. Williams, and B.S. Marmer, Thermal Destruction of *Escherichia coli* O157:H7 in Hamburger, 60 *J. Food Prot.* (vol. 10). 1163-1166 (1997) (demonstrating that, if hamburger does not get to 130°F, there is no bacterial destruction, and at 140°F, there is only a 2-log reduction of *E. coli* present).

<sup>38</sup> Griffin & Tauxe, *supra* note 12, at 72 (noting that, as a result, “fewer bacteria are needed to cause illness than for outbreaks of salmonellosis”). Nestle, *supra* note 4, at 41. (“Foods containing *E. coli* O17:H7 must be at temperatures high enough to kill all of them.”) (*italics in original*)

as twenty (20) organisms may be sufficient to infect a person and, as a result, possibly kill them.<sup>39</sup> And unlike generic *E. coli*, the O157:H7 serotype multiplies at temperatures up to 44°F, survives freezing and thawing, is heat resistant, grows at temperatures up to 111°F, resists drying, and can survive exposure to acidic environments.<sup>40</sup>

17. And, finally, to make it even more of a threat, *E. coli* O157:H7 bacteria are easily transmitted by person-to-person contact.<sup>41</sup> There is also the serious risk of cross-contamination between raw meat and other food items intended to be eaten without cooking. Indeed, a principle and consistent criticism of the USDA *E. coli* O157:H7 policy is the fact that it has failed to focus on the risks of cross-contamination versus that posed by so-called improper cooking.<sup>42</sup> With this pathogen, there is ultimately no margin of error. It is for this precise reason that the USDA has repeatedly rejected calls from the meat industry to hold consumers primarily responsible for *E. coli* O157:H7 infections caused, in part, by mistakes in food handling or cooking.<sup>43</sup>

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<sup>39</sup> Patricia M. Griffin, *et al.* Large Outbreak of *Escherichia coli* O157:H7 Infections in the Western United States: The Big Picture, in RECENT ADVANCES IN VEROCYTOTOXIN-PRODUCING *ESCHERICHIA COLI* INFECTIONS, at 7 (M.A. Karmali & A. G. Goglio eds. 1994). (“The most probable number of *E. coli* O157:H7 was less than 20 organisms per gram.”) There is some inconsistency with regard to the reported infectious dose. Compare Chryssa V. Deliganis, Death by Apple Juice: The Problem of Foodborne Illness, the Regulatory Response, and Further Suggestions for Reform, 53 Food Drug L.J. 681, 683 (1998) (“as few as ten”) with Nestle, *supra* note 4, at 41 (“less than 50”). Regardless of these inconsistencies, everyone agrees that the infectious dose is, as Dr. Nestle has put it, “a miniscule number in bacterial terms.” *Id.*

<sup>40</sup> Nestle, *supra* note 4, at 41.

<sup>41</sup> Griffin & Tauxe, *supra* note 12, at 72. The apparent “ease of person-to-person transmission...is reminiscent of Shigella, an organism that can be transmitted by exposure to extremely few organisms.” *Id.* As a result, outbreaks in places like daycare centers have proven relatively common. Rangel, *supra* note 15, at 605-06 (finding that 80% of the 50 reported person-to-person outbreak from 1982-2002 occurred in daycare centers).

<sup>42</sup> See, e.g. National Academy of Science, *Escherichia coli* O157:H7 in Ground Beef: Review of a Draft Risk Assessment, Executive Summary, at 7 (noting that the lack of data concerning the impact of cross-contamination of *E. coli* O157:H7 during food preparation was a flaw in the Agency’s risk-assessment), <http://www.nap.edu/books/0309086272/html/>.

<sup>43</sup> *Kriefall v. Excel*, 265 Wis.2d 476, 506, 665 N.W.2d 417, 433 (2003). (“Given the realities of what it saw as consumers’ food-handling patterns, the [USDA] bored in on the only effective way to reduce or eliminate food-borne illness”—i.e., making sure that “the pathogen had not been present on the raw product in the first place.”) (citing Pathogen Reduction, 61 Fed. Reg. at 38966).



18. Richard West purchased and consumed a Quarter-Pounder meal on October 2, 2024 at the McDonald's franchise operated by Sapphire located at 207 Jefferson Street, Belgrade, MT 59714. While consuming the burger, which contained onions, he shared bites of it with his 11-month-old daughter, L.W.
19. Both Richard and L.W. became symptomatic on or about October 4, 2024, with Richard initially suffering stomach cramps and L.W. becoming irritable around the same time. The condition of both continued to worsen over the next days.
20. By October 5, 2024, L.W. had severe and ongoing diarrhea and vomiting, and was unable to retain any of the formula or soft foods she was given.
21. Shortly thereafter, Richard began suffering from severe nausea and vomiting, eventually developing diarrhea which would last nearly two weeks.
22. On October 7, 2024, L.W. was taken to St. Peter's Hospital in Helena by her mother due to ongoing symptoms and her inability to retain fluids or food.
23. L.W. was admitted and given IV fluids and a test for pathogens, which later was positive for *E. coli* O157:H7.
24. L.W. remained hospitalized until October 14, 2024.
25. Richard did not receive medical treatment for his related illness because he was responsible for caring for his four other children while his wife remained at the hospital with L.W.
26. Both Richard and L.W. have recovered significantly from their illnesses, but both continue to suffer sensitive stomachs in the aftermath.

**COUNT 1 - Strict Liability**

27. Plaintiff incorporates by reference and makes a part of this count each foregoing paragraph of this Complaint.

28. At all times relevant hereto, the Defendants were manufacturers and sellers of the adulterated food product that is the subject of the action. As to McDonalds and Sapphire, the adulterated food product was the contaminated Quarter-Pounder burger that Plaintiff purchased and he and L.W. consumed on October 2, 2024.
29. The adulterated food product that the Defendants manufactured, distributed, and/or sold was, at the time it left the Defendants' control, defective and unreasonably dangerous for its ordinary and expected use because it contained *E. coli* O157:H7, a potentially deadly pathogen.
30. The adulterated food product that the Defendants manufactured, distributed, and/or sold was delivered to Plaintiff without any change in its defective condition. The adulterated food product that the Defendants manufactured, distributed, and/or sold was used in the manner expected and intended, and was consumed by Plaintiff and L.W.
31. The Defendants owed a duty of care to Plaintiff and L.W. to design, manufacture, and/or sell food that was not adulterated, that was fit for human consumption, that was reasonably safe in construction, and that was free of pathogenic bacteria or other substances injurious to human health. The Defendants breached this duty.
32. The Defendants owed a duty of care to Plaintiff L.W. to design, prepare, serve, and sell food that was fit for human consumption, and that was safe to the extent contemplated by a reasonable consumer. The Defendants breached this duty.
33. Plaintiff and L.W. suffered injury and damages as a direct and proximate result of the defective and unreasonably dangerous condition of the adulterated food product that the Defendants manufactured, distributed, and/or sold.

## **COUNT 2 - Breach of Warranty**

34. The Plaintiff incorporates by reference and makes a part of this count each foregoing paragraph of this Complaint.
35. The Defendants produced, distributed, and sold the contaminated food product that injured Plaintiff and L.W. and caused their *E. coli* O157:H7 infection. The Defendants are, therefore, manufacturers, distributors, and/or sellers of an adulterated food product, and the adulterated food product reached Plaintiff without substantial change from the condition in which it was sold by the Defendants.
36. The Defendants are subject to liability to the Plaintiff for their breaches of express and implied warranties made to Plaintiff with respect to the food product sold to her, including the implied warranties of merchantability and of fitness for a particular use. Further, the Defendants expressly warranted, through the sale of food to the public, and by the statements and conduct of their employees and agents, that the food product ultimately sold to Plaintiff was fit for human consumption, and not otherwise adulterated or injurious to health.
37. The food product sold by the Defendants and ultimately consumed by Plaintiff and L.W., which product was contaminated with *E. coli* O157:H7 and related filth and adulteration, would not pass without exception in the trade, and was thus in breach of the implied warranty of merchantability.
38. Plaintiff further alleges that the contaminated food sold by the Defendants and consumed by Plaintiff and L.W. was not fit for the uses and purposes intended by either Plaintiff or the Defendants, *i.e.*, human consumption, and that this product was therefore in breach of the implied warranty of fitness for its intended use.

39. As a further direct and proximate result of the conduct of the Defendants and their agents, servants, and/or employees as aforesaid, Plaintiff and L.W. suffered *E. coli* O157:H7 infections and the adverse effects associated with the same, as described in previous paragraphs of this complaint.
40. As a further direct and proximate result of the conduct of the Defendants and their agents, servants, and/or employees, Plaintiff and L.W. were forced to endure great pain, suffering, and inconvenience and may endure the same in the future. L.W. was forced to submit to medical care and may be forced to submit to the same in the future.
41. As a further direct and proximate result of the conduct of the Defendants and their agents, servants, and/or employees, Plaintiff and L.W. suffered an inability to perform the activities of daily living or some of them.

### **COUNT 3 - Negligence**

42. Plaintiff incorporates by reference and makes a part of this Count each foregoing paragraph of this Complaint.
43. The Defendants had a duty to comply with all statutory and regulatory provisions that pertained or applied to the manufacture, distribution, storage, labeling, and sale of the food product that injured Plaintiff and L.W., including the applicable provisions of the Federal Food Drug & Cosmetics Act, and similar Montana food and public health statutes
44. The food product that the Defendants manufactured and sold, and that Plaintiff purchased and Plaintiff and L.W. consumed, was adulterated within the meaning of the Federal Food Drug and Cosmetics Act and similar Montana statutes, because it contained a deleterious substance that rendered it injurious to health, i.e., *E. coli* O157:H7 bacteria.

45. The Defendants violated federal, state, and local food safety regulations by the manufacture and sale of adulterated food. These federal, state, and local food safety regulations are applicable here, and establish a positive and definite standard of care in the manufacture and sale of food. The violation of these regulations constitutes negligence as a matter of law.
46. Plaintiff and L.W. are in the class of persons intended to be protected by these statutes and regulations, and Plaintiff and L.W. were injured as the direct and proximate result of the Defendants' violation of applicable federal, state, and local food safety regulations.
47. The Defendants were negligent in the manufacture, distribution, and sale of a food product that was adulterated with *E. coli* O157:H7, not fit for human consumption, and not reasonably safe because adequate warnings or instructions were not provided.
48. Once the Defendants learned, or in the exercise of reasonable care should have learned, of the dangers associated with preparing and selling food, including, but not limited to, cross-contamination between foods, and the dangers associated with improperly cleaned or washed food, they had a duty to warn Plaintiff but failed to do so.
49. The Defendants had a duty to use supplies and raw materials in producing their food products that followed applicable federal, state, and local laws, ordinances and regulations; that were from reliable sources; and that were clean, wholesome, free from adulteration, and fit for human consumption, but failed to do so, and therefore breached that duty.
50. The Defendants were negligent in the selection of their suppliers, or other agents or subcontractors, and failed to adequately supervise them, or provide them with adequate standards, and, as a result, produced and sold food that was adulterated with *E. coli* O157:H7.

51. The Defendants had a duty to properly supervise, train, and monitor their employees, or the employees of their agents or subcontractors, engaged in the preparation and sale of their food products, to ensure compliance with the Defendants' operating standards and to ensure compliance with all applicable health regulations. The Defendants failed to properly supervise, train, and monitor these employees engaged in the manufacture, preparation and delivery of the food product ultimately sold to Plaintiff and thus breached that duty.
52. Defendants had a duty, given their knowledge of prior outbreaks of *E. coli* and other pathogenic bacteria in fresh produce, to take reasonable measures to ensure that the product utilized by the Defendants in their restaurant was safely manufactured and was not manufactured under conditions, generally, that are known, or reasonably should be known, to the food industry to be unsafe.

#### **COUNT 4 - Negligence Per Se**

53. Plaintiff incorporates by reference and makes a part of this Count each foregoing paragraph of this Complaint.
54. The Defendants had a duty to comply with all applicable state and federal regulations intended to ensure the purity and safety of their food products, including the requirements of the Federal Food Drug & Cosmetics Act and Montana State law.
55. Plaintiff and L.W. are in the class of persons intended to be protected by these statutes and regulations, and Plaintiff and L.W. were injured as the direct and proximate result of the Defendants' violation of applicable federal, state, and local food safety regulations.
56. The Defendants failed to comply with the provisions of the health and safety acts identified above, and, as a result, were negligent *per se* in their manufacture, distribution, and sale of food adulterated with *E. coli* O157:H7, a potentially deadly pathogen.

57. As a direct and proximate result of conduct by the Defendants that was negligent *per se*, Plaintiff and L.W. sustained injury and damages in an amount to be determined at trial.
58. Plaintiff reserves the right to amend the pleading to name the appropriate parties.

**WHEREFORE**, Plaintiff prays for judgment against Defendants as follows:

1. For all general and compensatory damages proved and awarded by the jury or court;
2. For all exemplary damages proved and awarded by the jury or court;
3. For all other damages allowed by law and awarded by the jury;
4. For Plaintiff's attorney fees and costs; and
5. For such other and further relief as the Court deems just and equitable under the circumstances allowable under Montana Law.

**JURY DEMAND**

1. Plaintiff hereby demands a jury trial on all claims triable by right.

Dated: October 31, 2024

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