



[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

My name is Dennis B. Brickman, P.E. I am an adult resident of Wilmette, Cook County, Illinois, I am over 21 years of age and am competent [REDACTED]

[REDACTED]

I personally maintain my CV, [REDACTED] Specifically, this record details my experience, education and training, [REDACTED]

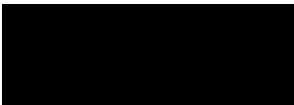
[REDACTED]

[REDACTED] This report details my expert opinions for this case, the facts and reasoning constituting the bases for my opinions, and qualifications, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]





4215 Campus Drive  
Aurora, IL 60504

**DENNIS B. BRICKMAN, P.E.**  
**PRINCIPAL**

[dbbrickman@engsys.com](mailto:dbbrickman@engsys.com)

Dennis Brickman is a Principal at ESI, a proven leader with a relentless, client-focused approach and a commitment to quality that has made him a trusted advisor to individuals, businesses, manufacturers, government agencies, and law firms. An industry veteran with over 35 years of mechanical engineering and materials science experience, Mr. Brickman is a staunch safety advocate with a passion for cutting through complexity and deploying technical expertise, tools and industry best practices in service to his clients. He has developed and delivered recommendations that range from the practical to the groundbreaking, and has helped clients successfully navigate a wide range of complex safety issues.

Mr. Brickman applies strong technical knowledge and real-world understanding of the design and manufacture of consumer products to help clients resolve safety concerns across the full product lifecycle — from product design, development, and manufacture to accident investigation, failure analysis, and product recall. As product safety is often related to interactions between people, machinery, and environment during manufacture and use, Mr. Brickman is frequently engaged to assess industrial and commercial equipment and facilities and provide guidance on product risk assessment, human factors and ergonomics, safeguarding, experimental testing, safety standards, safety training, and warnings and instructions. While his career has spanned many different industries, Mr. Brickman has also developed specialized expertise in the safety of children's products, outdoor power equipment, tree care machinery, elastic cord products, and automatic door sensor systems.

Mr. Brickman's commitment to safety is not limited to his every day consulting activities – he considers education and awareness an important part of his contributions to the field of safety. In addition to chairing over 20 engineering and human factors conference sessions, Mr. Brickman has been invited to speak at forums hosted by the U.S. Consumer Product Safety Commission, the American Society for Testing and Materials, the Safety Institute, and the Human Factors and Ergonomics Society. He has also performed interlock and lockout/tagout research for the National Institute of Occupational Safety and Health and developed training modules for OSHA. Well-regarded by his peers, Mr. Brickman's safety studies have been presented in regulatory proceedings, safety standards development committee meetings, equipment manufacturer forums, and litigation proceedings in the U.S. and abroad.

Mr. Brickman has published dozens of peer-reviewed technical papers, including The Safety Hierarchy issued by The National Safety Council. He has also provided expert testimony in product liability, premises liability, class action, patent, and intellectual property matters pending before both state and federal courts.

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## **Areas of Specialization**

Mechanical Engineering Systems  
Accident Analysis and Reconstruction  
Human Factors and Ergonomics  
Safety Engineering and Risk Assessment  
Product Safety and Design  
Experimental Testing and Failure Analysis  
Warnings and Instruction Manuals  
Safety Standards and Literature Research

## **Education**

M.S., Mechanical Engineering, Northwestern University, 1989  
B.S.E., Mechanical Engineering and Materials Science, Duke University, 1984

## **Licensed Professional Engineer (P.E.)**

State of Illinois .....License No. 062-045746  
State of Alabama.....License No. 28148-E  
State of Arkansas.....License No. 15796  
State of South Carolina.....License No. 36099

## **Professional Affiliations/Honors**

**Tau Beta Pi (National Engineering Honor Society), 1984**

**Graduation with Departmental Distinction in Mechanical Engineering and Materials Science**  
Duke University, December 1984

**Magna Cum Laude**  
Duke University, School of Engineering, 1984

**Class Honors**  
Duke University, 1982-1984

**Dean's List of the School of Engineering**  
Duke University, 1982-1984

**1983 Crane Company Engineering Scholarship**  
Duke University

**1984 R.H. Pinnix Engineering Scholarship**  
Duke University

**1987 American Society of Mechanical Engineers**  
Failure Prevention, Reliability, and Stress Analysis Award

**1991 American Society of Mechanical Engineers**  
Reliability, Stress Analysis, and Failure Prevention Award



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**1993 American Society of Mechanical Engineers**  
Reliability, Stress Analysis, and Failure Prevention Award

**American Society of Mechanical Engineers (ASME)**  
Member

**American Society of Safety Professionals (ASSP)**  
Member

**National Society of Professional Engineers (NSPE)**  
Member

**Illinois Society of Professional Engineers (ISPE)**  
Member

**International Society of Arboriculture (ISA)**  
Member

**International Society for Occupational Ergonomics & Safety (ISOES)**  
Member

**Institute of Scrap Recycling Industries**  
Member

## **Positions Held**

### **Engineering Systems Inc., Aurora, Illinois**

Principal, 2014 – Present  
Senior Managing Consultant, 2010 – 2014  
Senior Consultant, 2005 – 2010

### **Triodyne, Inc., Northbrook, Illinois**

Mechanical Engineering Safety and Design Consultant, 1985 – 2005  
Assistant Mechanical Engineering Safety and Design Consultant, 1983 – 1984

## **Professional Development**

1. Audit: ME 419 Design for Safety in Machines, Senior/Graduate Course, Illinois Institute of Technology, Chicago, IL, Spring, 1985.
2. "The 1985 National Conference on Products Liability Law," National Practice Institute, Inc., Chicago, IL, March 22-23, 1985.
3. "Defense Seminar on Products Liability Litigation," Legal Forum International, Chicago, IL, May 1, 1985.
4. "Human Factors Engineering and the Liability Interface," American Society of Agricultural Engineers Winter Meeting, Chicago, IL, December 17, 1985.
5. "International Agricultural Safety Issues," American Society of Agricultural Engineers Summer Meeting, San Luis Obispo, CA, July 2, 1986.



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6. "Design and Failure Prevention - Application," American Society of Mechanical Engineers Winter Meeting, Anaheim, CA, December 12, 1986.
7. "How Long Should a Product Last?" ASME Spring National Design Engineering Show & Conference, Chicago, IL, March 3, 1987.
8. "Fatigue and Fatigue Testing" and "Failure Prevention Through Stress Analysis and Reliability Methods," American Society of Mechanical Engineers 7th Biennial Conference on Failure Prevention and Reliability, Boston, MA, September 30, 1987.
9. "Weibull Analysis," "Design Case Studies," "Product Liability and Litigation," and "Design Procedures/Practice: Stress & Fatigue," American Society of Mechanical Engineers 8th Biennial Conference on Failure Prevention, Reliability and Stress Analysis, Montreal, Quebec, Canada, September 18, 1989.
10. "Analysis and Assessment: A Course in Practical Ergonomics," Illinois Safety Council, Chicago, IL, April 30, 1991.
11. "Reliability in Design," "Design Theory and Case Studies," and "Reliability of Engineering Materials," American Society of Mechanical Engineers 9th Biennial Conference on Reliability, Stress Analysis, and Failure Prevention, Miami, FL, September 24, 1991.
12. "Design Methods - I, II, & III," American Society of Mechanical Engineers 3rd International Conference on Design Theory and Methodology, Miami, FL, September 24, 1991.
13. "A New Trend in Quality Engineering," Dr. Genichi Taguchi, ASME National Design Engineering Show and Conference, Chicago, IL, February 25, 1992.
14. "Vehicular Risk Analysis," "Safety in Manufacturing," "Plant Hazards Screening and Risk Analysis," "Engineering Applications of Risk Analysis," "Improving Freight Train Performance," and "Mechanical Design and Rehabilitation - I & II," American Society of Mechanical Engineers Winter Annual Meeting, Anaheim, CA, November 9-10, 1992.
15. "Optimization, Reliability, and Safety Techniques," "Reliability and Probabilistic Design Analysis," and "Design Methods," American Society of Mechanical Engineers 10th Biennial Conference on Reliability, Stress Analysis, and Failure Prevention, Albuquerque, NM, September 20-21, 1993.
16. "Safety and Risk in the Chemical Process Industry - I," "The Role of Operator Training in Managing Technological Risk," "Failure Analysis and Prevention - I," "Symposium on Crashworthiness and Occupant Protection in Transportation Systems: Crashworthiness Methodologies," and "Product/Machine Safety," American Society of Mechanical Engineers Winter Annual Meeting, New Orleans, LA, November 29-30, 1993.
17. "Failure Analysis and Prevention," ASME 1994 International Mechanical Engineering Congress and Exposition of the Winter Annual Meeting, Chicago, IL, November 9, 1994.
18. "Design and Failure Prevention" and "Probabilistic Design, Failure Analysis, and Safety Methods," American Society of Mechanical Engineers 11th Biennial Conference on Reliability, Stress Analysis, and Failure Prevention, Boston, MA, September 18, 1995.
19. "Failure Analysis/Failure Prevention - I & II" and "Safety of Mechanical Equipment," ASME 1995 International Mechanical Engineering Congress and Exposition, San Francisco, CA, November 13, 1995.



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20. "Symposium on Transportation Risk," "Symposium on Risk in Emerging Technologies," "Failure Analysis and Prevention," and "Symposium on Human Factors Engineering," ASME 1996 International Mechanical Engineering Congress and Exposition, Atlanta, GA, November 20-21, 1996.
21. "Design, Failure Prevention and Stress Analysis," The 51st Meeting of the Society for Machinery Failure Prevention Technology and the 12th Biennial Conference on Reliability, Stress Analysis and Failure Prevention, Virginia Beach, VA, April 16, 1997.
22. "Symposium on Product Safety" and "Failure Analysis and Prevention - II," ASME 1997 International Mechanical Engineering Congress & Exposition, Dallas, TX, November 17-18, 1997.
23. "Symposium on Safety in Manufacturing and New Technologies" and "Symposium on Safety Analysis of Operating Systems," ASME 1998 International Mechanical Engineering Congress & Exposition, Anaheim, CA, November 19, 1998.
24. "Stress Analysis and Failure Prevention," "Application of Design in Everyday Problems," and "Application of Reliability and Stress Analysis in Everyday Life Problems," American Society of Mechanical Engineers 13th Biennial Reliability, Stress Analysis and Failure Prevention Conference, Las Vegas, NV, September 14-15, 1999.
25. "Symposium on Successfully Managing The Risk and Development of Your Business and Technology - Safety Through Design," ASME 2000 International Mechanical Engineering Congress & Exposition, Orlando, FL, November 7, 2000.
26. "The New Frontier of Product Safety at the End of Product Life," ASME 2001 International Mechanical Engineering Congress and Exposition, New York, NY, November 13, 2001.
27. "Panel on 3D: Design, Manufacturing and Safety" and "Safety Analysis and Lessons Learned After an Accident - II," ASME 2002 International Mechanical Engineering Congress & Exposition, New Orleans, LA, November 19, 2002.
28. "Applications in Safety Design," 2003 ASME Design Engineering Technical Conferences, Chicago, IL, September 4, 2003.
29. "Safety Improvement Through Design" and "Process Industry Safety Management," 2003 ASME International Mechanical Engineering Congress, Washington, DC, November 21, 2003.
30. "Accidents in Arboriculture: What's Happening And Why?" TCI EXPO '04, Detroit, MI, October 29, 2004.
31. "Returning the Space Shuttle Safely to Flight," "ASME Risk Analysis and Management for Critical Asset Protection - I & II," "Issues of Societal Vulnerability and Risk Based Methods - 1 & 2," "Space and Aerospace Risk and Reliability," "Reliability Methods and Applications," "Forensic Analysis and Product Liability Issues - 1 & 2," and "Medical and Patient Safety," 2004 ASME International Mechanical Engineering Congress and Exposition, Anaheim, CA, November 15-16, 2004.
32. "Warnings," "Vision and Ergonomics Design of Industrial Inspection Tasks," "Manual Material Handling," "Ergonomics in the Semiconductor Industry," "Slips and Falls 1 & 4," and "Human Factors 2 & 3," XIX Annual International Occupational Ergonomics and Safety Conference 2005, Las Vegas, NV, June 27-28, 2005.





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33. "Risk-Informed Design," "Risk Methods and Applications," "Methods and Tools for Complex Systems Reliability," and "Safety and Risk Studies," 2005 ASME International Mechanical Engineering Congress & Exposition, Orlando, FL, November 11, 2005.
34. "Forklift Operator Safety Training," Material Handling Services, Inc., Aurora, IL, December 28, 2005.
35. "The Role of Warnings and Instructions," The University of Wisconsin-Madison, Department of Engineering Professional Development, Madison, WI, March 21-23, 2006.
36. "A Risk Case History: Decisions on the Hurricane Protection System in New Orleans Prior to Katrina," "Reliability Management and Applications," "Mobile Equipment Reliability," "Workplace and Product Safety," and "Are Risk-Based Methods Mature Enough for Engineering Applications?" 2006 ASME International Mechanical Engineering Congress & Exposition, Chicago, IL, November 5-6, 2006.
37. "Pedestrian Vehicle Traffic Collisions," Northwestern University Center for Public Safety, Evanston, IL, November 13-15, 2006.
38. "OSHA 510: Standards for Construction Industry," Construction Safety Council, Hillside, IL, June 25-28, 2007.
39. "Safety at the Walt Disney Corporation," "Risk Analysis – 1 & 2," "Product or Process Safety – 1," and "Safety Engineering – 1 & 2," 2007 ASME International Mechanical Engineering Congress and Exposition, Seattle, WA, November 12 -13, 2007.
40. "OSHA 501: Trainer Course in Occupational Safety and Health Standards for General Industry," Northern Illinois University - Naperville, Illinois, July 21 – 24, 2008.
41. "Successful Training Techniques," 20th Annual Chicagoland Safety & Health Conference, Northern Illinois University – Naperville, Illinois, September 15, 2008.
42. "Forklift Operator Safety Training," Equipment Depot, Aurora, IL, October 23, 2008.
43. "Injury Mitigation in Rollovers," "Reliability Engineering 2," "Design Improvements for Auto Safety," "Product and Process Safety," and "Risk Informed Decision Making," 2008 ASME International Mechanical Engineering Congress and Exposition, Boston, MA, November 4, 2008.
44. "The ABC's of Human Behavior and Safety Performance," TCI EXPO, Milwaukee, WI, November 13, 2008.
45. "30 Years in Ergonomics," "Ergonomic Applications and Assessment-I," "Safety Issues-I," "Falling Injuries in the Aged," "Emerging Trends in Australian Construction Safety-Opportunities for Safety Professionals," "Slips and Falls," and "Construction Symposium-II," XXIst Annual International Occupational Ergonomics and Safety Conference 2009, Dallas, TX, June 11-12, 2009.
46. "General Safety Engineering," "Auto and Truck Safety and Consumer Product Safety," "Risk Analysis," "Reliability Methods and Applications," and "Risk Analysis for Multi-Hazards," 2009 ASME International Mechanical Engineering Congress and Exposition, Lake Buena Vista, FL, November 18, 2009.



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47. "Health and Safety Issues in the Hospitality Industry and How They've Changed," "Ergonomic Applications and Assessment-I," "Safety Issues," and "Connect & Communication," XXIInd Annual International Occupational Ergonomics and Safety Conference 2010, Tempe, AZ, June 10, 2010.
48. "Risk Analysis Topics 4," "Bobsled Special Plenary Presentation," "Mechanism Dynamics," and "Safety Engineering Topics," 2010 ASME International Mechanical Engineering Congress & Exposition, Vancouver, British Columbia, Canada, November 17, 2010.
49. "Tree Care Safety Forum," Winn, MI, January 12, 2011.
50. "Product Design and Testing," "Techniques and Methodology," "Ergonomics and Photography," "Ergonomic Applications and Assessment-II," and "Safety Issues," XXIIIrd Annual International Occupational Ergonomics and Safety Conference, Baltimore, MD, June 9-10, 2011.
51. "ANSI Z133 and The Every Day Tree Trimmer," TCI Expo, Hartford, CT, November 5, 2011.
52. "Energy and Water: Two Vital Commodities," "National Occupational Research Agenda Initiatives for Safety and Health in Manufacturing," "Safety Issues and Applications," "Safety in Transportation," "Risk Analysis and Reliability Methods," and "Forensic Evaluation of Safety," ASME 2011 International Mechanical Engineering Congress and Exposition, Denver, Colorado, November 14-15, 2011.
53. "Forklift Operator Safety Training," Equipment Depot, Aurora, IL, December 12, 2011.
54. "Aging in the 21st Century: Opportunities and Challenges," "Human Performance," "Healthcare and Forensic Ergonomics," "Ergonomic Issues," and "Reflections of a Pioneer in Ergonomics," XXIVth Annual International Occupational Ergonomics and Safety Conference, Ft. Lauderdale, FL, June 7, 2012.
55. "AWPT Operator Training," Stevenson Sales & Service, South Holland, IL, November 21, 2012.
56. "A Decade of Challenges and Opportunities in Occupational Ergonomics and Safety," "Biomechanics," "Human Factors," "Accident Reconstruction," and "Comparison of Ergonomic Process Implementation in Four U.S. Corporations," XXVth Annual Occupational Ergonomics and Safety Conference, Atlanta, GA, June 6, 2013.
57. "Chipper Operator Specialist Training Program," Tree Care Industry Association Tree Care Academy, Lisle, IL, September 18, 2013.
58. "The Concussion Crisis in Athletics – What Have We Learned Since 2007," "Traumatic Brain Injury: From Prevention to Rehabilitation," "Medical Errors, Prevention and Recovery," "Consumer Product Safety Commission," "Current Transportation Safety Issues," "UTV/ATV Issues," "Home Safety and Children," and "Drowning Prevention – Emerging Strategies and Interventions," A National Discussion on Injury Prevention, The Safety Institute, Rosemont, IL, September 24-25, 2013.
59. "A Systems Approach to Civil Works Transformation," "Ergonomics-1," and "Safety & Warnings," The 2nd Annual World Conference of the Society for Industrial and Systems Engineering, Las Vegas, NV, November 5-6, 2013.
60. "AEM Product Liability Seminar," AEM, Schaumburg, IL, May 1, 2014.



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61. "Challenges in Major Limb Re-plantation – Treatment After Protective Measures Have Failed," "Safety-I," "Ergonomics in Construction Industry," and "Ergonomics-II," XXVI Annual International Occupational Ergonomics and Safety Conference, El Paso, TX, June 5, 2014.
62. "Human Factors & Ergonomics-I," "Quality Control in IE-I," and "Observations from Over 25 Years in Engineering Education and Administration," The 3rd Annual World Conference of the Society for Industrial and Systems Engineering, San Antonio, TX, October 20, 2014.
63. "Safety Engineering & Management and Risk Analysis" and "Forensic Applications & Failure Analysis I," ASME 2014 International Mechanical Engineering Congress & Exposition, Montreal, Quebec, Canada, November 19, 2014.
64. "A System's Approach for Evaluating and Managing Patient Transfer in a Large Hospital," "Case Studies and Applications," "Ergonomics in Construction Industry," and "Other Topics in Ergonomics & Safety," XXVIIth Annual International Occupational Ergonomics and Safety Conference, Nashville, TN, May 28, 2015.
65. "Designing for Children: What Do Human Factors Professionals Need to Know?" "Modeling Problems in the Workplace: Human Reliability, Errors, and Workload," "Interactive Posters," and "Training in Applied Settings," 2015 International Annual Meeting of the Human Factors and Ergonomics Society, Los Angeles, CA, October 29, 2015.
66. "Powered Industrial Truck Operator Safety Training Program," Atlas Toyota Material Handling, Aurora, IL, December 1, 2015.
67. "Systems Design," "Modeling and Simulation for Defense Applications," "Process Modeling and Analysis," and "Problem Solving," 2016 General Donald R. Keith Memorial Capstone Conference, Department of Systems Engineering, United States Military Academy, West Point, NY, April 28, 2016.
68. "Failure Analysis & Prevention and Plastic Pipe & Fittings: Failure Prevention and Slow Crack Growth," Society of Plastics Engineers Annual Technical Conference, Indianapolis, IN, May 23, 2016.
69. "The Ergonomics of Ergonomics: Have We Missed The Obvious?" "Case Studies and Applications – I," "Case Studies and Applications – II," "Occupational Ergonomics," and "A Picture is Worth 1000 Words: Demonstrative Exhibits in Litigation," XXVIIIth Annual International Occupational Ergonomics and Safety Conference, Chicago, IL, June 9, 2016.
70. "Arborist Safety: May The Odds Always Be In Your Favor," TCI Expo, Baltimore, MD, November 10, 2016.
71. "Failure Analysis: Case Studies and Expert Panel," Society of Plastics Engineers Annual Technical Conference, Anaheim, CA, May 10, 2017.
72. "Neck Biomechanics for Ergonomics: Lessons Learned and Challenges Ahead," "Prevention Through Design and Reconstruction," "Employee Health and Wellness," "Risk Assessment and Risk Perception," "Education/Training – Ergonomics, Safety and Sustainability," "Panel Discussion – Research to Practice to Research," and "From Patient Handling to Materials Handling – A Journey of an Ergonomist," XXIXth Annual International Society of Occupational Ergonomics & Safety Conference, Seattle, WA, June 1, 2017.
73. "IPAF AWP Operator Training," Skyjack Equipment Inc., St. Charles, IL, October 31, 2017.



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74. "Machinery Safety – Virtual Symposium," The American Society of Safety Engineers, March 20, 2018.
75. "Human Dimensional Variability: A Safety Problem and Opportunity," "Occupational Ergonomics," "Biomechanics and Work Physiology," "Workplace Safety and Health," "Case Studies and Applications," and "From Research to Design: Footwear and Ladder Design for Preventing Falling Accidents," XXXth Annual International Occupational Ergonomics and Safety Conference, Pittsburgh, PA, June 7, 2018.
76. "Webinar: Risk Management Tools for Safety Professionals," American Society of Safety Professionals, September 6, 2018.
77. "Powered Industrial Truck Operator Safety Training Program," Atlas Toyota Material Handling, Aurora, IL, January 22, 2019.
78. "CPSC Lab Tour," "Reverse Recall: An Analysis of Product Recall from End to Beginning," "A Computer Generated Reality is Worth 1000 Words," "CPSC Keynote Presentation," "CPSC Plenary Session: #ASKCPSC," "CPSC Plenary Session: Compliance Programs and FOIA," "Two Philosophies: One Goal," "Technology: A Powerful Tool for Improving Recall Effectiveness," and "Think Like a Consumer: Proactive Safety Engineering," 2019 ICPHSO Annual Meeting and Training, Washington, DC, February 25-27, 2019.
79. "Machine Safeguarding Seminar" and "Risk Control Agricultural Equipment Guarding Damage/Removal," ASSP Safety 2019 Professional Development Conference, New Orleans, LA, June 12, 2019.
80. "Occupational Safety and Health," "Prevention Through Design I," "Prevention Through Design II," "Virtual/Augmented Reality – Wearable Technology," and "Application of Ergonomics," XXXIst Annual International Occupational Ergonomics and Safety Conference, New Orleans, LA, June 12, 2019.
81. "Concrete Power Buggy Safety Training," Safety Provisions, Inc., April 1, 2020.

### **Professional Activities**

1. Vice-Chairman, "Fatigue and Fatigue Testing," American Society of Mechanical Engineers 7th Biennial Conference on Failure Prevention and Reliability, Boston, MA, September 30, 1987.
2. Chairman, "Design Procedures/Practice: Stress & Fatigue," American Society of Mechanical Engineers 8th Biennial Conference on Failure Prevention, Reliability and Stress Analysis, Montreal, Quebec, Canada, September 18, 1989.
3. Chairman, "Reliability in Design," American Society of Mechanical Engineers 9th Biennial Conference on Reliability, Stress Analysis, and Failure Prevention, Miami, FL, September 24, 1991.
4. American Society of Mechanical Engineers, Reliability, Stress Analysis, and Failure Prevention Steering Committee, September 11, 1992 to present.
5. Vice-Chairman, "Optimization, Reliability, and Safety Techniques," American Society of Mechanical Engineers 10th Biennial Conference on Reliability, Stress Analysis, and Failure Prevention, Albuquerque, NM, September 20, 1993.



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6. Chairman, "Probabilistic Design, Failure Analysis, and Safety Methods," American Society of Mechanical Engineers 11th Biennial Conference on Reliability, Stress Analysis, and Failure Prevention, Boston, MA, September 18, 1995.
7. Chairman, "Symposium on Product Safety," American Society of Mechanical Engineers 1997 International Mechanical Engineering Congress & Exposition, Dallas, TX, November 17, 1997.
8. Chairman, "Symposium on Safety in Manufacturing and New Technologies," American Society of Mechanical Engineers 1998 International Mechanical Engineering Congress & Exposition, Anaheim, CA, November 19, 1998.
9. Co-Chairman, "Application of Design in Everyday Problems," American Society of Mechanical Engineers 13th Biennial Reliability, Stress Analysis and Failure Prevention Conference, Las Vegas, NV, September 14, 1999.
10. Co-Chairman, "Applications in Safety Design," 2003 American Society of Mechanical Engineers Design Engineering Technical Conferences, Chicago, IL, September 4, 2003.
11. Co-Chairman, "Human Factors 3," XIX Annual International Occupational Ergonomics and Safety Conference 2005, Las Vegas, NV, June 28, 2005.
12. Chairman, "Safety and Risk Studies," 2005 ASME International Mechanical Engineering Congress & Exposition, Orlando, FL, November 11, 2005.
13. Co-Chairman, "Workplace and Product Safety," 2006 ASME International Mechanical Engineering Congress & Exposition, Chicago, IL, November 6, 2006.
14. Co-Chairman, "Product or Process Safety – 1," 2007 ASME International Mechanical Engineering Congress and Exposition, Seattle, WA, November 13, 2007.
15. Topic Co-Organizer, "Product and Process Safety," 2008 ASME International Mechanical Engineering Congress and Exposition, Boston, MA, November 4, 2008.
16. Session Co-Organizer, "General Safety Engineering," 2009 ASME International Mechanical Engineering Congress and Exposition, Lake Buena Vista, FL, November 18, 2009.
17. Chair, "Ergonomic Applications and Assessment-II," XXIIIrd Annual International Occupational Ergonomics and Safety Conference, Baltimore, MD, June 9, 2011.
18. Chair, "Accident Reconstruction," XXVth Annual Occupational Ergonomics and Safety Conference, Atlanta, GA, June 6, 2013.
19. Chair, "Safety-I," XXVI Annual International Occupational Ergonomics and Safety Conference, El Paso, TX, June 5, 2014.
20. Chair, "Human Factors & Ergonomics-I," The 3rd Annual World Conference of the Society for Industrial and Systems Engineering, San Antonio, TX, October 20, 2014.
21. Chair, "Case Studies and Applications," XXVIIth Annual International Occupational Ergonomics and Safety Conference, Nashville, TN, May 28, 2015.
22. Judge, 2016 General Donald R. Keith Memorial Capstone Conference, Department of Systems Engineering, United States Military Academy, West Point, NY, April 28, 2016.



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23. Chair, "Case Studies and Applications – I," XXVIIIth Annual International Occupational Ergonomics and Safety Conference, Chicago, IL, June 9, 2016.
24. Chair, "Prevention Through Design and Reconstruction," XXIXth Annual International Society for Occupational Ergonomics & Safety Conference, Seattle, WA, June 1, 2017.

## Publications

1. Brickman, Dennis, "Press Rolls and Petrography," Vertices, Spring, 1985, p. 33.
- 2a. Barnett, Ralph L., and Brickman, Dennis B., "Safety Hierarchy," Triodyne Safety Brief, Vol. 3, No. 2, June 1985, pp. 1-6.
  - b. Journal of Safety Research, Vol. 17, No. 2, Summer, 1986, pp. 49-55.
- 3a. Brickman, Dennis B., and Barnett, Ralph L., "On Rubber Augers - Failure Modes and Effects," ASAE 86-5018, St. Joseph, MI, American Society of Agricultural Engineers, 1986, pp. 1-15.
  - b. Triodyne Safety Brief, Vol. 4, No. 2, June 1986, pp. 1-7.
  - c. Transactions of the ASAE, Vol. 29, No. 5, September-October 1986, pp. 1208-1212.
4. Brickman, Dennis B., and Pearsall, George W., "Stress and Strength Analysis of a Granite Press Roll," ASME 86-WA/DE-21, New York, American Society of Mechanical Engineers, 1986, pp. 1-4.
5. Brickman, D.B., "Effect of Tensile Prestress on the Fatigue of Rock Drill Bits," Failure Prevention and Reliability-1987, New York, American Society of Mechanical Engineers, 1987, pp. 91-93.
- 6a. Barnett, Ralph L., and Brickman, Dennis B., "Deadman Controls on Lawn Mowers and Snowblowers," Triodyne Safety Brief, Vol. 5, No. 2, July 1988, pp. 1-13.
  - b. Failure Prevention and Reliability - 1989, New York, American Society of Mechanical Engineers, 1989, pp. 59-68.
7. Brickman, Dennis B., "Use of Extreme Value Statistics in the Characterization of Ergonomic Strength Data," Master's Thesis, Northwestern University, 1989.
8. Brickman, Dennis B., "Ergonomic Studies of Grip Strength - Literature Review," Triodyne Safety Brief, Vol. 6, No. 2, June 1990, pp. 1-15.
- 9a. Brickman, Dennis B., and Barnett, Ralph L., "Auger Elevator-Failure Modes and Effects Case Study," Reliability, Stress Analysis, and Failure Prevention - 1991, DE-Vol. 30, New York, American Society of Mechanical Engineers, 1991, pp. 95-102.
  - b. Triodyne Safety Brief, Vol. 9, No. 2, January, 1994, pp. 1-8.
- 10a. Brickman, Dennis B., and Barnett, Ralph L., "On the Problem of Guarding Three Roll-Bending Machines," ASME 92-WA/SAF-3, New York, American Society of Mechanical Engineers, 1992, pp. 1-8.
  - b. Triodyne Safety Brief, Vol. 9, No. 3, January, 1994, pp. 1-9.



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- 11a. Brickman, Dennis B., "Design Methodology For Predicting Ergonomic Grip Strength," 1992 Advances in Bioengineering, BED-Vol. 22, New York, American Society of Mechanical Engineers, 1992, pp. 517-519.
- b. Triodyne Safety Brief, Vol. 8, No. 4, July, 1993, pp. 13-15.
- 12a. Brickman, Dennis B., and Barnett, Ralph L., "Quantification Versus Go/No-Go Criteria," Reliability, Stress Analysis, and Failure Prevention - 1993, DE-Vol. 55, New York, American Society of Mechanical Engineers, 1993, pp. 9-15.
- b. Triodyne Safety Brief, Vol. 10, No. 4, April, 1995, pp. 1-7.
- 13a. Brickman, Dennis B., and Barnett, Ralph L., "On the Safety of Stationary Buffing Machines," Safety Engineering and Risk Analysis, SERA - Vol. 1, New York, American Society of Mechanical Engineers, 1993, pp. 103-110.
- b. Triodyne Safety Brief, Vol. 11, No. 1, April, 1995, pp. 1-8.
- 14a. Brickman, Dennis B., and Barnett, Ralph L., "Strongest Link Principle," ASME 94-WA/DE-2, New York, American Society of Mechanical Engineers, 1994, pp. 1-6.
- b. Triodyne Safety Bulletin, Vol. I, No. 3, August, 1995.
- 15a. Brickman, Dennis B., "On the Safety of Agricultural Disc Mowers," Proceedings of the 1995 Design Engineering Technical Conferences, DE-Vol. 83, Vol. 2, New York, American Society of Mechanical Engineers, 1995, pp. 107-113.
- b. Triodyne Safety Abstract, Vol. 1, No. 2, September, 1995.
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2. "On Rubber Augers - Failure Modes and Effects," International Agricultural Safety Issues, American Society of Agricultural Engineers Summer Meeting, San Luis Obispo, CA, July 2, 1986.
3. "Stress and Strength Analysis of a Granite Press Roll," Design and Failure Prevention - Application, American Society of Mechanical Engineers Winter Annual Meeting, Anaheim, CA, December 12, 1986.
4. "Effect of Tensile Prestress on the Fatigue of Rock Drill Bits," Fatigue and Fatigue Testing, American Society of Mechanical Engineers 7th Biennial Conference on Failure Prevention and Reliability, Boston, MA, September 30, 1987.
5. "The Expert Witness and Engineering Ethics," Illinois Society of Professional Engineers North Shore Chapter Meeting, Mt. Prospect, IL, October 15, 1987.
6. "Deadman Controls on Lawn Mowers and Snowblowers," Design Case Studies, American Society of Mechanical Engineers 8th Biennial Conference on Failure Prevention, Reliability and Stress Analysis, Montreal, Quebec, Canada, September 18, 1989.
7. "Auger Elevator-Failure Modes and Effects Case Study," Design Theory and Case Studies, American Society of Mechanical Engineers 9th Biennial Conference on Reliability, Stress Analysis, and Failure Prevention, Miami, FL, September 24, 1991.
8. "On the Problem of Guarding Three Roll-Bending Machines," Safety in Manufacturing, American Society of Mechanical Engineers Winter Annual Meeting, Anaheim, CA, November 9, 1992.
9. "Design Methodology for Predicting Ergonomic Grip Strength," Mechanical Design and Rehabilitation - II, American Society of Mechanical Engineers Winter Annual Meeting, Anaheim, CA, November 10, 1992.
10. "Auger Elevator - Failure Modes and Effects Case Study," and "On the Problem of Guarding Three Roll-Bending Machines," guest lecturer, ME 419 Design for Safety in Machines, Illinois Institute of Technology, Chicago, IL, February 2, 1993.
11. "Quantification Versus Go/No-Go Criteria," Optimization, Reliability, and Safety Techniques, American Society of Mechanical Engineers 10th Biennial Conference on Reliability, Stress Analysis, and Failure Prevention, Albuquerque, NM, September 20, 1993.
12. "On the Safety of Stationary Buffing Machines," Product/Machine Safety, American Society of Mechanical Engineers Winter Annual Meeting, New Orleans, LA, November 30, 1993.
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15. "Juvenile Product Safety," Children's Memorial Hospital Medical Clinic, Chicago, IL, September 13, 1995.
16. "On the Safety of Agricultural Disc Mowers," Probabilistic Design, Failure Analysis, and Safety Methods, American Society of Mechanical Engineers 11th Biennial Conference on Reliability, Stress Analysis, and Failure Prevention, Boston, MA, September 18, 1995.



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17. "Portable Luggage Cart Safety – An Application of the Safety Hierarchy," Failure Analysis/Failure Prevention II, ASME 1995 International Mechanical Engineering Congress and Exposition, San Francisco, CA, November 13, 1995.
18. "On the Safety of a Portable Grinder Guard," Safety of Mechanical Equipment, ASME 1995 International Mechanical Engineering Congress and Exposition, San Francisco, CA, November 13, 1995.
19. "Product Safety," Children's Memorial Hospital, Chicago, IL, February 27, 1996.
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21. "The Grate Debate," Symposium on Human Factors Engineering, ASME 1996 International Mechanical Engineering Congress and Exposition, Atlanta, GA, November 21, 1996.
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24. "Pen Cap Failure Analysis and Prevention," Failure Analysis and Prevention - II, ASME 1997 International Mechanical Engineering Congress & Exposition, Dallas, TX, November 18, 1997.
25. "Safety Analysis of Roller Compactors Exposed to Rollover," Construction Industry Manufacturers Association Winter Week '97 Product Safety Council Seminar, Niles, IL, December 11, 1997.
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27. "Commercial Walk-Behind Lawn Mower Failure Analysis Case Study," Stress Analysis and Failure Prevention, American Society of Mechanical Engineers 13th Biennial Reliability, Stress Analysis and Failure Prevention Conference, Las Vegas, NV, September 14, 1999.
28. "Trencher-Impingement on Buried Objects," Application of Reliability and Stress Analysis in Every Day Life Problems, American Society of Mechanical Engineers 13th Biennial Reliability, Stress Analysis and Failure Prevention Conference, Las Vegas, NV, September 15, 1999.
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31. "On the Safety of Infeeding Vertical Garden Shredders," The New Frontier of Product Safety at the End of Product Life, ASME 2001 International Mechanical Engineering Congress and Exposition, New York, NY, November 13, 2001.



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35. "Bumpers/Fenders Used For Low Speed Runover Protection," Applications in Safety Design, 2003 American Society of Mechanical Engineers Design Engineering Technical Conferences, Chicago, IL, September 4, 2003.
36. "On the Safety of Infeeding Commercial Tree Chippers," Safety Improvement Through Design, 2003 ASME International Mechanical Engineering Congress, Washington, DC, November 21, 2003.
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38. "Safety Testing of Consumer Oven Broiler Doors With Live Children," Forensic Analysis and Product Liability Issues-2, 2004 ASME International Mechanical Engineering Congress and Exposition, Anaheim, CA, November 16, 2004.
39. "Limited Movement Machinery Roller Devices," Forensic Analysis and Product Liability Issues-2, 2004 ASME International Mechanical Engineering Congress and Exposition, Anaheim, CA, November 16, 2004.
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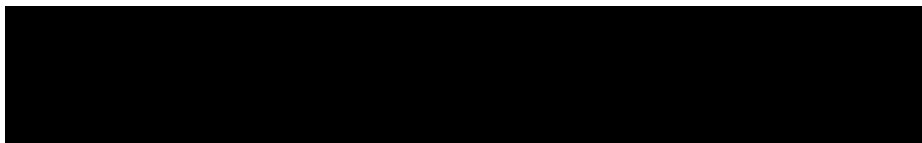
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69. "Failure Analysis of a Plastic Toy Helicopter," Failure Analysis & Prevention and Plastic Pipe & Fittings: Failure Prevention and Slow Crack Growth, Society of Plastics Engineers Annual Technical Conference, Indianapolis, IN, May 23, 2016.
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72. "Beach Rental Elevator Child Entrapment Safety Analysis," Case Studies and Applications – I, XXVIIIth Annual International Occupational Ergonomics and Safety Conference, Chicago, IL, June 9, 2016.
73. "Preventing Failures in Elastomeric Resistance Bands," Failure Analysis: Case Studies and Expert Panel, Society of Plastics Engineers Annual Technical Conference, Anaheim, CA, May 10, 2017.
74. "Tanker Truck Loading Platform Fall Protection Accident Reconstruction Analysis," Prevention Through Design and Reconstruction, XXIXth Annual International Society for Occupational Ergonomics & Safety Conference, Seattle, WA, June 1, 2017.
75. "A Picture is Worth 1000 Words: Seeing the Unwitnessed Facts in Accidents," PLP&D 2017 Fall Workshop, Rosemont, IL, October 12, 2017.



Dennis B. Brickman, P.E.  
*April 2020*

76. "Stump Grinder Accident Reconstruction and Design Testing Methodologies," Case Studies and Applications, XXXth Annual Occupational Ergonomics and Safety Conference, Pittsburgh, PA, June 7, 2018.
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82. "Optional Safety Equipment," DRI Product Liability Conference, New Orleans, LA, February 5, 2020.





**DEDIOS (EST OF DAKOTAH) V. EPOCH EVERLASTING PLAY, ET AL**  
ESI Project No: 74316A



4215 Campus Drive  
Aurora, IL 60504

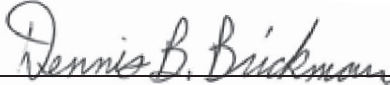


**DEDIOS (EST OF DAKOTA) V. EPOCH EVERLASTING PLAY, ET AL**  
ESI Project No: 74316A




**John (Jack) Walker, III, Esq.**  
Martin Walker PC  
121 N. Spring Avenue  
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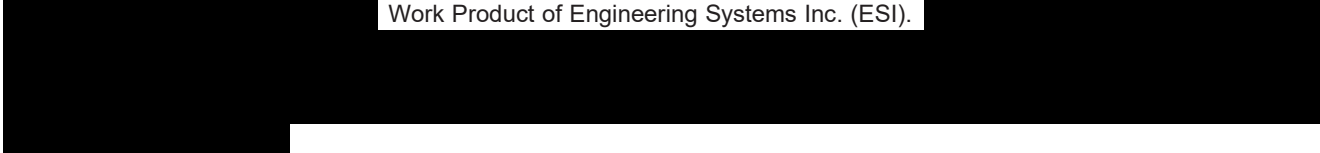
  
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Dennis B. Brickman, P.E.  
Principal  
IL P.E. | Expires: November 30, 2021



**Reviewed by:**

  
\_\_\_\_\_  
Anne C. Mathias, P.E.  
Senior Managing Consultant  
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Work Product of Engineering Systems Inc. (ESI).  






█.	Background of Dennis B. Brickman, P.E.	█
█	Documents Reviewed	█
█	Methodology	█
█.	Description of Dakotah Dedios's Incident	█
█.	Exemplar Product Inspection	█
█.	Safety Regulations, Standards, Guides and Literature	█
█	Epoch Everlasting Play (EEP) Corporate and Calico Critters Product History	█
█	Epoch Everlasting Play/Calico Critters/Sylvanian Families Background	█
█.	Safety Analysis	█
█	Summary of Opinions	█

On 11/21/19, Engineering Systems Inc. (ESi) was retained by Martin Walker P.C. on behalf of S. Maria Schmidt as personal representative for the estate of Dakotah Dedios to investigate the circumstances surrounding the fatality of 33 month old Dakotah Dedios involving her putting a Calico Critters Yellow Labrador Twins toy pacifier in her mouth, resulting in an upper airway obstruction, at her residence in Jicarilla, New Mexico on 5/10/18. The pathologist who examined Dakotah Dedios identified that the cause of death was choking by the toy pacifier that was aspirated and found in Dakota Dedios's bronchus during the autopsy. Richaline Dedios purchased the subject Calico Critters Yellow Labrador Twins and pacifier and bottle accessories product from Walmart in Bernalillo, New Mexico on 5/5/18. [REDACTED], I have reviewed the documents and other materials described below and have inspected an exemplar product at issue. [REDACTED]

#### **I. Background of Dennis B. Brickman, P.E.**

I hold a BSE in Mechanical Engineering and Materials Science from Duke University in 1984. Honors that I achieved at Duke University include Graduation with Departmental Distinction, Magna Cum Laude, Class Honors, Dean's List of the School of Engineering, Crane Company Engineering Scholarship, R.H. Pinnix Engineering Scholarship, and Tau Beta Pi (National Engineering Honor Society). Some of my completed coursework at Duke University includes Structure and Properties of Solids, Product Safety and Design, Mechanical Design, and Failure Analysis and Prevention. I received a MS in Mechanical Engineering from Northwestern University in 1989. Some of my completed coursework at Northwestern University includes Human Factors, Engineering Law, and Manufacturing Processes. My Master's Thesis covered the topic of human factors grip strength. In addition, I have completed 81 continuing professional development courses covering such areas as safety design, consumer product safety, human factors engineering, human behavior and performance, risk assessment, designing for children, warnings and instructions, product reliability, and failure prevention.

I have participated in numerous professional activities over the past 35 years. I am a member of the American Society of Safety Engineers, American Society of Mechanical Engineers, National Society of Professional Engineers, Illinois Society of Professional Engineers, International Society for Occupational Ergonomics & Safety, and Institute of Scrap Recycling Industries. I have served on the Steering Committee for the American Society of Mechanical Engineers Committee for Reliability, Stress Analysis and Failure Prevention and have received three awards from this Committee. I have been the chairman or co-chairman of 22 engineering conferences, including such titles as Reliability in Design, Symposium on Product Safety, Symposium on Safety in Manufacturing and New Technologies, Human Factors, Workplace and Product Safety, Ergonomic Applications and Assessment, and Product or Process Safety. I am a Licensed Professional Engineer in Illinois, Alabama, Arkansas, and South Carolina.

Throughout my professional career, I have published 74 technical papers and have made 83 professional presentations across the country. I have lectured and published technical papers on numerous engineering design and human factors safety issues, including the

areas of designing products for children and the hazards associated with children placing toys and other small parts in their mouth. In particular, I have given professional presentations regarding child product safety to pediatricians at Children's Memorial Hospital in Chicago, Human Factors and Ergonomics Society, ASTM, U.S. CPSC, American Society of Mechanical Engineers, The Safety Institute, Society for Industrial and Systems Engineering, and International Occupational Ergonomics and Safety. In addition, I have authored three peer-reviewed technical publications associated with children placing toys and small parts in their mouth published by the American Society of Mechanical Engineers.

My safety research activities include performing independent children's product testing, including products associated with U.S. CPSC recalls and ASTM safety standards development. Also, I have assisted in developing OSHA training modules. In addition, I have completed the OSHA 501 Trainer Course in Occupational Safety and Health Standards for General Industry. I have conducted safety audits of industrial manufacturing facilities and testing laboratories. Furthermore, I have consulted on the safety analysis and design of several products being introduced in the field.

I currently am employed as a Principal at Engineering Systems Inc. (ESI), a multi-disciplinary professional engineering consulting firm and laboratory headquartered in Aurora, Illinois. My specialty areas include mechanical engineering safety and design of consumer products and human factors. For over 35 years, I have conducted hundreds of consumer product incident investigations, including toy products. My current curriculum vitae is attached to this report.

## **Documents Reviewed**

- A. Complaint and Plaintiff's Complaint for Wrongful Death, Loss of Consortium, Personal Injury and Punitive Damages.
- B. Medical records (NMU School of Medicine, Jicarilla EMS, and San Juan Regional Medical Center).
- C. Exemplar product photographs and autopsy photographs.
- D. Epoch Bates documents: 000001-000821.
- E. Plaintiff's First Set of Requests for Production and Interrogatories to Defendant, Epoch Everlasting Play, LLC.
- F. Defendants Walmart, Inc. & Marie Short's Initial Disclosures.
- G. Walmart, Inc.'s Answers and Responses to Plaintiff Maria Schmidt, as Personal Representative for the Estate of Dakotah Dedios, Deceased, and Richaline Dedios' First Set of Interrogatories and Request for Production to Defendant Walmart, Inc.



- H. Walmart Document Production; Bates numbered WM\_Schmidt\_00000001-WM\_Schmidt\_00000317.
- I. CPSC In Depth Investigation (IDI).
- J. Scheduling Order and Expert Deadline extension.
- K. Depositions and exhibits of Danelle Renee Dedios, Richaline Jonelle Dedios, Anna Vreeland, and Alyssa Masterson.
- L. 16 CFR Part 1501 – Method for Identifying Toys and Other Articles Intended for Use by Children Under 3 Years of Age which Present Choking, Aspiration, or Ingestion Hazards Because of Small Parts (2018).
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- P. Barnett, Ralph L., and Brickman, Dennis B., Safety Hierarchy, Journal of Safety Research, Vol. 17, No. 2, Summer, 1986, pp. 49-55.
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- BB. Guidance Document No. 11, On the Application of the Directive on the Safety of Toys (88/378/EEC), 2009.
- CC. ISO/IEC Guide 37:2012, Instructions for Use of Products by Consumers.
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- EE. U.S. CPSC Handbook for Manufacturing Safer Consumer Products, 2006.
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- VV. Calico Critters – Good for a 4 Year Old?, Mamapedia, 2012.
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### **III. Methodology**

The methodology utilized in my analysis of Dakota Dedios's fatal incident includes the classic systems approach published by the National Safety Council, which considers the interaction between the human user, the product, and the environment and how an incident relates to that system. In addition, the safety hierarchy methodology was utilized as published in the peer-reviewed National Safety Council Journal of Safety Research in 1986. A further methodology utilized in my analysis of the subject incident is the evaluation of relevant safety regulation and standard requirements and the application of mechanical engineering principles.

### **IV. Description of Dakotah Dedios's Incident**

The [REDACTED] description of the subject incident was given in Richaline Dedios's deposition:

Dakotah Dedios was in the living room with Richaline Dedios's mom and dad. Richaline Dedios was called by her nephew that Dakotah Dedios was choking. Richaline Dedios's dad said Dakota Dedios had been choking on a Cheeto. Dakotah Dedios stopped breathing before the ambulance arrived. Dakotah Dedios passed away because the Calico Critters toy pacifier was lodged in Dakotah Dedios's airway and it did not allow her to breathe.

### **V. Exemplar Product Inspection**

An inspection of an exemplar Calico Critters Yellow Labrador Twins product, including the bottle and pacifier accessories, associated with Dakotah Dedios's incident was conducted at Engineering Systems Inc. (ESi) in Aurora, Illinois on 7/15/20. Photographs, measurements, and testing using the small parts cylinder were performed during this inspection. Figure 1 [REDACTED] shows the exemplar Calico Critters Yellow Labrador Twins and the bottle and pacifier accessories fitting entirely within the small parts cylinder.

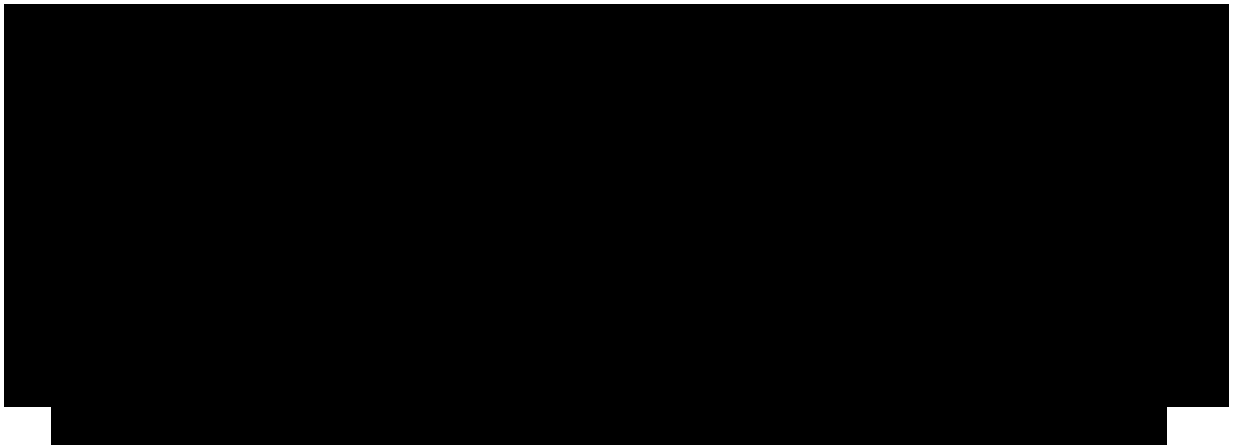


Figure 2 depicts the exemplar Calico Critters Yellow Labrador Twins package where the bottle and pacifier accessories are not visible.



Figure 2. Exemplar CC Yellow Labrador Twins Package – Accessories Not Visible

Figure 3 shows the size of the exemplar Calico Critters Yellow Labrador Twins pacifier accessory (approximately 0.388 inches wide and approximately 0.440 inches deep), which is typically smaller than an adult's pinky fingernail.



Figure 3. Exemplar CC Yellow Labrador Twins Pacifier (0.388" x 0.440")

An inspection was also conducted of the Calico Critters Yellow Labrador Twins product supplied with the car accessory instead of the bottle and pacifier accessories. The Calico Critters Yellow Labrador Twins car accessory (approximately 1 inch wide by 2.125 inches long) [REDACTED]

[REDACTED]

■ [REDACTED]

[REDACTED]

■ [REDACTED]

[REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]



[REDACTED]

■

[REDACTED]

1.

[REDACTED]

■

[REDACTED]

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[REDACTED]

■

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

D. 16 CFR Part 1117 – Reporting of Choking Incidents Involving Marbles, Small Balls, Latex Balloons and Other Small Parts (2018)

The purpose of this part is to set forth the Commission’s interpretative regulations for reporting of choking incidents required by the Child Safety Protection Act. The statute requires that each manufacturer, distributor, retailer, and importer of a marble, small ball, or latex balloon, or other small part, shall report to the Commission any information obtained by such manufacturer, distributor, retailer, or importer which reasonably supports the conclusion that an incident occurred in which a child (regardless of age) choked on such a marble, small ball, latex balloon, or other small part contained in such toy or game and, as a result of that incident the child died, suffered serious injury, ceased breathing for any length of time, or was treated by a medical professional. (1117.1)

█ [REDACTED]

█ [REDACTED]

█ [REDACTED]

█ [REDACTED]

█ [REDACTED]

█ [REDACTED]

█ [REDACTED]

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█ [REDACTED]

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3.

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J. ANSI 2, Guidelines for Organizing a Product Safety Program, 1978

1. Manufacturers have a responsibility to produce products that satisfy the safety expectations of society. These expectations have recently accelerated, with the result that safety must receive more emphasis than ever before in decisions concerning the design, production, and marketing of products, and including ultimate intended and foreseeable uses. (p. 1)
2. Procedures and reporting channels should be established for obtaining useful information about product complaints, incidents, accidents, and related injuries. Consumer comments reaching a company through nonstandard channels should be made part of reports and summaries, as applicable. (p. 3)

3. Evaluation and review – A hazard evaluation should be made of products of new design or those having significant design revisions. Comparisons to applicable safety standards and regulations should be made. (pp. 3-4)
4. Safety, legal, and engineering reviews should be made of advertising and sales materials. Sales, distributor, dealer, installation, and service personnel should be included in education, motivation, and training activities concerned with their product safety responsibilities. (p. 4)

K. ISO 10377:2013, Consumer Product Safety – Guidelines for Suppliers

1. This International Standard provides practical guidance for suppliers of all sizes to assist them in assessing and managing the safety of the consumer products they supply – from the design of the product, to the input of raw materials, to production, to distribution, to retail and to the final product end-user and disposal. This International Standard is intended to be particularly valuable to small and medium-sized enterprises, as well as to suppliers that do not design or produce products, but are still responsible for their safety. (p. v)
2. It is important that suppliers maintain an awareness of and comply with the laws and regulations of the countries where the products are manufactured, imported, distributed or sold. (p. vi)
3. The key issues for all members in the supply chain (designers, manufacturers, importers, distributors and retailers) include the following:
  - a. designing safety into the consumer product.
  - b. identifying the potential hazards associated with their products.
  - c. determining or estimating exposure to the potential hazard.
  - d. assessing the risks to consumer health and safety.
  - e. managing these risks by eliminating or reducing them to a tolerable level.
  - f. providing consumers with hazard warnings and instructions essential to the safe use and disposal of the products.
  - g. approving any change or substitution of design, materials, or production processes. (pp. 5-6)
4. The organization should ensure that those involved in consumer product safety, whether they are internal or external to the organization, have the



necessary education, training, technical knowledge and experience for carrying out their responsibilities. (p. 7)

5. The organization should establish and maintain procedures to record, control, retain and retrieve all principal documents and data that reflect safety in design, production and the marketplace. These items should include the following:
  - Records required to comply with laws and regulations;
  - Documents created during management of safety in design (hazard analysis and hazard reduction plan; significant design choices and safety decisions);
  - Design testing and inspection;
  - Compliance with regulatory requirements and product specific industry standards;
  - Third-party testing and conformity assessment, as required;
  - Documents created during management of safety in marketplace (consumer complaints and consumer product safety incidents; product literature, including advertising, marketing and packaging; communications with suppliers and consumers, including feedback from buyers; corrective actions) (pp. 7-8)
6. Documents created should reflect information and records retained from the original design, production and marketplace, as well as those generated as a response to potential hazards, issues, complaints and reviews about the organization's products. All written responses should be placed in the organization's own product files to record that the organization considered all available information about the product, its hazards and its risks. (p. 8)
7. The organization should ensure that continual improvement of the safety of their consumer product(s) becomes established as a part of the organizational culture. These activities can range from minor to major improvements in the organization and/or its supply chain.

Fundamental to effective and efficient improvement is making informed decisions on the basis of evaluation of information collected and the incorporation of lessons learned. The organization should define objectives for the improvement of its products and processes based on that analysis.

In particular, continual improvement should apply to safety in consumer product design, production and the marketplace, e.g.:

- Improvement activities in design might include using focus groups to anticipate the product's use in different situations and determining how the product performs or is viewed by different groups;

- Improvement activities in the marketplace might include, but not limited to, receiving supplier or consumer comments or complaints and gathering a small team to propose design or production changes or other corrective actions.

All continual improvement activities and their outcomes should be documented and reviewed by management regularly to ensure continual improvement, as outlined in its product safety management plan. (p. 9)

8. Suppliers should provide information to consumers on the safety features of the consumer product. This may include labelling or advertising that addresses product use. Examples of topics addressed in labelling or advertising are age-appropriate use, potential choking, product contents, or other product hazards. (p. 12)
9. Suppliers should obtain information from consumers about their use of the consumer product. Examples where this information may be obtained include consumer feedback during marketing, consumer complaints to the supplier, consumer information provided during claims and lawsuits, and consumer reports made to regulatory bodies. Suppliers should catalog this consumer information for use during the continual improvement of the product. Suppliers should provide information on how to report incidents to the supplier and how to detect potential safety hazards. (p. 13)
10. The safety-related considerations that contribute to the design specification should include, but not be limited to, the following:
  - intended use;
  - foreseeable use and misuse;
  - compliance with mandatory safety requirements and industry standards;
  - exposure analysis;
  - hazard identification and characterization;
  - risk assessment;
  - risk reduction;
  - risk communication. (p. 14)
11. Suppliers should have an understanding and knowledge of the consumer product's intended uses and knowledge of how it will actually be used. This knowledge can be derived from information such as the following:
  - the use of a product based on factual human behavior (e.g. a young child explores its surrounding by placing toys in his/her mouth) or measurements of the human body;
  - the use of a product based on feedback from consumers, including their claims, returns, warranties, repairs and lawsuits;

- the use of a product based on the institutional knowledge of the supplier (e.g. actual knowledge held by the supplier and accumulated over many years);
- the use of the product that is consistent with the laws and regulations in the location where the product will be used;
- the use of a product that is consistent with industry knowledge for that particular product. (p. 15)

12. Suppliers should have a clear understanding and knowledge of how a consumer product could be misused or misassembled and should make appropriate adjustments to the product design. This knowledge can be derived from information such as the following:

- the use of a product based on factual human behavior or measurements of the human body (e.g. children);
- the use of a product based on feedback from consumers, including their claims, returns, warranties, repairs and lawsuits;
- demographics information from marketing and consumer trends;
- the use of a product based on the institutional knowledge of the supplier;
- the use of a product that is consistent with industry knowledge for that particular product. (p. 15)

13. Hazard identification involves the identification of any potential hazards associated with the consumer product that may result in harm (injury) from the foreseeable use or misuse of the product, its components and packaging.

Data and information for hazard identification may come from various sources, e.g.:

- a. consumer complaints and returns from similar products.
- b. incident reports, injury data and analysis of databases.
- c. recall data from various government and independent sources.
- d. requirements in laws, regulations and international, national and industry standards.
- e. product or raw material test reports or certificates, as appropriate.
- f. state of the art independent industrial, expert and scientific knowledge and advice.
- g. relevant ergonomic principles.

- h. internet chat groups, forums and social media outlets.
    - i. other sources of information related to the product and similar products. (p. 16)
- 14. The organization should establish a process for conducting risk evaluation when it is determined that there is a hazard posed which has the potential to cause harm. The risk evaluation process will generally include the following steps:
  - a. evaluation of the type of injury that may occur and the corresponding severity level, e.g. fatal versus non-fatal.
  - b. estimation of the probability of harm occurring, taking into consideration consumer behavior and the frequency and duration of use of the product.
  - c. estimation of the risk to each of the identified consumer groups from the hazards identified.
  - d. documentation of the risk evaluation.
  - e. verification by experts of the application of the risk evaluation method and conclusions reached.
  - f. If the risk is not tolerable, then continuing with risk reduction by redesigning the product or by providing protective measures against the hazard. (p. 18)
- 15. The ultimate goal of carrying out risk assessment is to assist the organization in determining how best to reduce the risk and what action needs to be taken. The organization should compare the risk assessment results against what is determined to be tolerable risk, taking into consideration social and public benefits. If a tolerable risk is not achieved, it may be necessary to take further steps to reduce the risk to a tolerable level. If the risk cannot be reduced to a tolerable or acceptable level, the product should not be permitted to reach the marketplace. (pp. 19-20)
- 16. Documentation of the design specification process is important to demonstrate both that it was done and how it was done. The history of the consumer product design and development, including evolution of the product design, the history of other similar products and history of incidents or problems with the product or similar products should be documented. By creating, maintaining and updating these documents, the organization can ensure that information is available to be used during subsequent risk evaluation activities and for traceability, product redesign

and legal and regulatory compliance. The organization should therefore establish and maintain procedures to record, control, retain and retrieve all principal documents and data related to design, production and the marketplace. (p. 21)

17. To improve consumer product safety, suppliers should conduct pre-purchase confirmation, proactive data collection, and ongoing product risk assessment. (p. 26)
18. Data collection and analysis provides a supplier with the information necessary to identify trends in consumer product safety, from information such as defects, return rates, repairs, product incidents, complaints, claims and legal actions. Proactive data collection and analysis is also valuable as feedback for the risk reduction and continual improvement processes. Data collection and analysis may also be required by some government regulations. (p. 27)
19. The supplier should establish processes for data collection and analysis by means such as the following:
  - establishing, communicating and promoting a consumer complaint system, which is a systematic way of obtaining information on how consumers use products, failure modes and defects, and opportunities to improve the product.
  - using new data to constantly update the understanding of risks inherent in a product and how to reduce them. (pp. 27-28)
20. In accordance with ISO 10393, suppliers should establish a process for documenting and investigating incidents and defects involving the product. (p. 28)
21. A process for documenting and investigating reports of incidents and defects involving the consumer product should be established.
  - the organization should make it easy for users of the product to file product incident reports;
  - document the product the product incident or defect details, the investigation, the findings and the actions taken;
  - assign competent staff to investigate the incident or defect, and to check for trends; determine if the incident or defect report is valid and, if possible, acquire the product involved in the actual incident for review;
  - provide regulators or competent authorities, certification bodies and other stakeholders with product incident and defect reports, the investigation findings and the actions taken at the frequency and level of detail required by legal and contractual requirements;
  - perform a risk assessment if the evaluation identifies a harm or potential harm;

- identify and implement corrective actions to eliminate or reduce the reoccurrence of the defect, e.g. depending on the level of risk, this can be accomplished by redesign of the product to remove the potential harm, guarding against the potential harm or by informing the users of the potential harm;
- determine if the defect is common to other products and, if so, require that similar corrective actions be implemented;
- check that the corrective actions achieve the desired goal in reducing the potential for the defect to reoccur (p. 33)

22. Risk evaluation is the logical identification and evaluation of any hazards that a product may pose, and the determination of the likelihood that a consumer or user will be exposed to them. Once the potential hazards and their cause have been identified, it is then possible to determine the risk posed and, if required, to redesign the product or add protective devices before the product is produced or reaches the consumer. (p. 35)

23. Supplier responsibilities:

Monitoring and continual improvement:

- a. market surveillance
- b. recall management (p. 40)

24. Implement and document safety process:

Marketplace:

- a. establish a post market surveillance system;
- b. identify key safety indicators;
- c. reverse flow analysis for early detection of emerging issues;
- d. risk analysis for informed decision making (e.g. product withdrawal/recall). (p. 41)

L. ISO 10393:2013, International Standard: Consumer Product Recall – Guidelines for Suppliers.

1. In order to determine the need for a product recall, the supplier should have in place a process for acting upon receipt of information that a product has created harm, or has the potential to create harm. (p. 8)

2. For situations where a very serious injury or substantial property damage could occur, consideration should be given to implementing a product recall, even if the probability of risk cannot be accurately determined. (p. 9)
3. Suppliers should have in place a system for collecting information on product incidents and communicating these to stakeholders, as necessary.  
  
As required by regulatory requirements and contractual obligations, the supplier should notify regulators, certification bodies and other organizations of reports that a product has created harm, or has the potential to create harm. (p. 9)
4. The supplier should establish a process for investigating product incidents or potential incidents. (p. 9)
5. The supplier should implement corrective actions to reduce the probability of the incident reoccurring. This can be accomplished by initiatives such as redesigning the product to remove the potential harm and redesigning labels. (p. 21)

M. ISO/IEC Guide 50-2002, Safety Aspects – Guidelines for Child Safety.

1. CAUTION – The absence of reported injury does not necessarily mean that there is no hazard. (p. 3)
2. In the first year or two of life children appear to have no sense of danger. Thus, whereas normally allowance can be made for hazards that are obvious to the user and are necessary for the function of the product, these hazards might not be so obvious for children. (p. 5)
3. Certain behavioral characteristics associated with early childhood also render children at risk of injury. These include the following:
  - putting things into their mouths (mouthing), particularly in the first three years of life, exposing them to ingestion and aspiration risks.
  - natural inquisitiveness and exploring behavior. (p. 5)
4. Since young children explore by mouth, products that are for use by, or likely to be used around, children should not have small easily removable parts. (p. 5)
5. Children cannot necessarily be expected to recognize the difference between a real object and an imitation or model, either of which might be harmful. (p. 6)
6. Strategies to avoid or reduce risks due to small parts include the following:

- eliminating small parts.
- providing age-appropriate guidance and warnings to consumers of the hazards for younger children.
- applying secondary prevention strategies such as providing continuous air passages, so that if the part is inhaled the child can still breathe. (p. 10)

N. ISO/IEC Guide 50-2014, Safety Aspects – Guidelines for Child Safety in Standards and Other Specifications.

1. Passive strategies work without the individual having to take any action to be protected, whereas active strategies require the individual to take some action to minimize the harm. Passive strategies that eliminate or guard against a hazard ensure a greater likelihood of success than active strategies.

Improving product safety, i.e. eliminating or minimizing risks that may lead to significant injuries, should start at the product design stage, aiming to incorporate a primary prevent approach or, if this is not possible, a secondary approach. Secondary prevention can include the provision of information for users about residual risks, those that might have to be addressed by users. Whenever possible, product design should aim to incorporate passive prevention strategies. (pp. 3-4).

2. Various sources can be used to identify the potential for harm associated with a product. These include, but are not limited to:
  - injury statistics;
  - detailed information available from injury surveillance systems;
  - research results;
  - investigations of case reports;
  - complaint data;
  - extrapolation of relevant data about hazardous characteristics from other types of products. Surveillance data, recalls, and other similar actions in other jurisdictions should be considered. (p. 4)
3. The identification of countermeasures results from research and evaluation, particularly based on injury data, child behavior, engineering and biomechanics. Feedback, e.g. from consumers, can provide valuable information about the need to redesign products. (p. 4)
4. One of the most frequently observed exploration strategies is object manipulation. In infancy, this often involves handling and mouthing objects simultaneously. Exploratory mouthing is not just about eating. Children's mouths are relatively sensitive and mouthing provides children with feelings of pleasure as well as alleviation of pain associated with



teething. Some mouthing behavior continues well beyond the early stages of exploration. (p. 8)

5. Children cannot be expected to recognize the difference between a real object and an imitation or model, either of which can be harmful. (p. 10)
6. Small objects and parts of products present potentially serious hazards, especially to toddlers and young children. Small objects can enter the airway, trachea, and oesophagus, blocking airflow to the lungs.

The following hazardous situations can occur:

- a. objects can be inhaled or inspired, lodging in the trachea or deeper within the airway, causing asphyxia;
- b. objects can be ingested, lodging in the oesophagus at the aortic arch, causing airway obstruction which can result in asphyxia;
- c. objects can be ingested, presenting risks of blockage or perforation of the oesophagus, stomach or intestines;
- d. objects can be inserted into other body orifices, leading to pain, swelling, obstruction or disease. (p. 22)

O. ISO/IEC Guide 37 (2012).

1. The instructions for use can be on the product itself or its packaging, or in accompanying materials, e.g. leaflets, manuals, media and computerized information such as the product supplier's website. (p. v)
2. Instructions for use cannot and should not compensate for design deficiencies. (p. 1)
3. Instructions for use should be integrated and the information should be consistent with all other material about the same product issued by the manufacturer/producer (such as advertising, packaging, any warranty and internet-based information). There should be consistency in all instructional and promotional materials, including markings, labels and shipping containers. (p. 1)

P. ISO 26000:2010, Guidance on Social Responsibility.

1. Details of products and services provided by suppliers play an important role in purchasing decisions because this information may provide the only data readily available to consumers. Unfair, incomplete, misleading or deceptive marketing and information can result in purchase of products

and services that do not meet consumer needs, and result in a waste of money, resources and time, and may even be hazardous to the consumer. (pp. 53-54)

2. When communicating with consumers, an organization should:
  - not engage in any practice that is deceptive, misleading, fraudulent or unfair, unclear or ambiguous, including omission of critical information.
  - Give primary consideration in advertising and marketing to the best interests of vulnerable groups, including children, and not engage in activities that are detrimental to their interests. (p. 54)

Q. AS-NZS 8124.1-2002, Safety of Toys – Part 1: Safety Aspects related to Mechanical and Physical Properties.

[REDACTED]

A primary consideration should be the potential choking and aspiration hazards associated with small parts. Children under the age of three are more prone to placing objects in their mouths. However, the propensity to put non-food objects in the mouth does not disappear at the chronological age of three years. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



- S. Trade Practices Act 1974 – Consumer Protection Notice No. 14 of 2013 – Consumer Product safety Standard: Toys for Children up to and Including 36 Months of Age.

Toys for Children up to and including 36 months of age, being objects manufactured, designed, labelled or marketed as playthings, including, but not limited to: stuffed, plush and flocked animals and figures.

- T. U.S. CPSC Handbook for Manufacturing Safer Consumer Products, 2006

1. A foreseeable use analysis considers the potential ways that a consumer will interact with and/or operate a product. It is a critical step in designing a safe consumer product. Foreseeable use includes the use as intended by the manufacturer, and also use in ways that were not intended but can reasonably be expected to occur. (p. 9)
2. Distribution practices significantly influence the safety of consumer products. Accordingly, control over final packaging and shipping operations is necessary. This control includes the selection of adequate packaging materials and design of methods of packaging. (p. 13)
3. Product safety policy: The commitment of the manufacturer is the first executive step to be taken in developing an industrial consumer product safety system. A clear, strong statement from senior management citing statutory and voluntary reasons for this commitment is needed. The policy should be explicit with respect to the primacy of product safety during design, production and distribution. This policy should also make clear that it applies not only to the internal operations but also to suppliers, including suppliers of products manufactured outside the U.S. (p. 17)
4. Design Review: Design review is an examination of materials, configuration, packaging and labeling for purposes of identifying potential product hazards. Design review consists of:

Identification and evaluation of potential safety hazards against pre-established criteria appropriate to the product. It is particularly important that these criteria include objective projections of the conditions under which the product is used, including recognition of the age levels and physical limitations of users.

Appropriate corrective action must be taken when product safety hazards are identified. Adequate records must be maintained showing the details of the hazard and subsequent corrective actions taken. (p. 21)

U. U.S. CPSC Manufacturer’s Guide to Developing Consumer Product Instructions (October 2003)

1. You should not expect instructions, regardless of how well they are written, to overcome poor product design or problems such as:

- hazards that are difficult to perceive, appreciate, or control.
- contradictory messages consumers may infer from the features or marketing of the product. (p. 2)

2. Find out consumers’ attitudes and beliefs about your product.

You might monitor web sites and chat areas where consumers comment on products. For example, some web sites allow consumers to post their own reviews of products they have used. The information you get from web sites is not systematic or comprehensive, but reading this information is a convenient way to “listen in” on real consumer beliefs and attitudes. (p. 9)

V. Step 6: Best Practices, U.S. CPSC, [www.cpsc.gov](http://www.cpsc.gov).

The following Best Practices posted on the CPSC website ([www.cpsc.gov](http://www.cpsc.gov)) constitute official agency guidance.

1. In addition to meeting the legal requirements described on the Business Education page, you – as a manufacturer or importer – should take additional steps to ensure that your product not only meets or exceeds the requirements of federal safety laws, but also is designed and manufactured as safely as possible. (p. 1)

2. Be Knowledgeable and Aware of the Business and Regulatory Environment

- Review consumer feedback and assess the safety of your product in light of the information provided to your company through consumer service calls, online consumer reviews, and by monitoring feedback about your product provided to CPSC by consumers using SaferProducts.gov, CPSC’s publicly searchable consumer database.
- Study your legal responsibility to report information about your product that indicates (i) it may fail to comply with CPSC requirements, (ii) it is defective and could create a substantial risk of

injury, (iii) is otherwise unreasonably hazardous or dangerous, or that the product is subject to reporting for legal reasons.

- Monitor recalls of products similar to your through e-mail notification, SaferProducts.gov, Recalls.gov, Twitter, our RSS feed. (p. 2)
- 3. Designers should seek to eliminate risk, guard against risk, or warn users of identified risks, in that order. This “safety hierarchy” is a recognition that the safest approach to el
- 4. In addition to CPSC’s free Handbook for Manufacturing Safer Consumer Products, an international standard is available for purchase that can help you in this process. ISO 10377:2013 “Consumer Product Safety – Guidelines for Suppliers.” This guidance is intended for suppliers and has valuable advice, including sections on “safety in design,” “safety in production,” and “safety in the marketplace.” (p. 3)
- 5. Monitoring news and recalls in your industry can give you an excellent sense of the issues your industry faces. CPSC will expect you, as a business, to be fully conversant in the issues and concerns facing your industry. You should review CPSC’s recall listings, which may be searched by “Product Type” and can provide useful information about CPSC recalls relating to products similar to yours. You should consider signing up for our recall emails. You should review and understand those recalls so that your company doesn’t make the same mistakes. (p. 4)
- 6. Monitoring safety reports about your products and similar products in the marketplace also can help provide useful information. You can obtain this type of information by monitoring direct consumer feedback, information from your retailers, information from consumer online reviews and e-tailers, and consumer reports on our publicly searchable database of consumer reports of harm at [www.SaferProducts.gov](http://www.SaferProducts.gov). (p. 4)
- 7. Here is CPSC’s Web page about recall planning and here is an international standard that can help you develop a plan (ISO 10393:2013; Consumer Product Recall – Guidelines for Suppliers). (p. 5)

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

[REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

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■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

BB. Final Report on Economic Assessment of the Small Parts Regulation, U.S. CPSC, April 1979, p. 8.

For those firms with products that still may not meet the requirements, the costs of eliminating small parts problems are expected to be small in most cases. Frequently, the necessary adjustments will involve little more than removing a small part which does not change the fundamental nature of the toy. For example, a miniature farm, including a barn, fence, and farm animals might fail only because one of the smaller figures, such as a chicken, might fit entirely within the test cylinder. Removal of this figure would allow this toy to meet the requirements of the regulation with no other changes. Of course, the manufacturer would also have the option of making the figure larger and meeting the requirements in that way.

[REDACTED]

[REDACTED]

DD. A Physiological Review of Toys Causing Choking in Children, U.S. CPSC, 1989.

The current small parts test cylinder addresses choking hazards from toys or other articles intended for use by children under three by eliminating objects small enough to enter the child's lower throat and air passages. (Executive Summary)

EE. U.S. CPSC Small Parts Briefing Package, 1979.

If a toy's carton recommends "For children ages 2-5," it is likely that purchasers of that toy will give it to children of those ages. However, it is also likely that some purchasers will buy the toy for precocious children who are 1.5 years old. Thus, despite the labeling, such a toy will automatically be used by children for whom the manufacturer does not intend it.

FF. Guidelines for Relating Children's Ages to Toy Characteristics, U.S. CPSC, 1985.

1. Once critical toy characteristics are identified, and the appropriate ages of the toy users determined, the toy should be designed so that it is safe for those users. (p. 5)
2. Age appropriateness issues for certain products may change as children's interests are substantially altered by availability of new toys, advertising, and promotion of toys. (pp. 5-6)
3. Size of toy/toy parts has three elements. First, the overall dimensions of the toy (weight, volume, length and width) are considered, especially as they affect ease of handling the toy for a child of a particular age. Second, the number and size of parts of the toy are considered, especially in relation to what the child can be expected to handle at a particular age and what the child is likely to prefer. A third element is the construction of the toy – are parts removable. (p. 15)
4. It is not until after 18 months that most children exhibit the pretend activity with objects that involves constructing and/or playing with miniature play scenes. Before this age children may enjoy handling or carrying around little people and animals, or doing simple relational activities such as placing people into cars. (p. 163)
5. Two-year-olds prefer a variety of accessories, even if they may be unable to understand the specific uses of all the accessories or pieces. Accessories should not be too small: children may have difficulty manipulating pieces smaller than 2 or 3 inches. (p. 164)
6. 19-24 months (1-1/2 to 2 years): accessories should not be small enough to be swallowed. (p. 166)
7. 25-36 months (2 to 3 years): accessories should not be small enough to be swallowed. (p. 168)





1.

[REDACTED]

■

[REDACTED]

characteristics and the characteristics of children of this age.  
(pp. 3-4)

■

[REDACTED]

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[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

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█ [REDACTED]

JJ. Guidance Document No. 11, On the Application of the Directive on the Safety of Toys (88/378/EEC), 2009.

1. The play value of a toy intended for children under 36 months could be determined by the following key factors:
  - a. Their attraction to objects “which are like them”: baby, small child, baby animal, etc.;
  - b. Their less developed physical abilities in terms of ease of movement, manual dexterity, etc. (the toy may be small and light for the child to handle it easily).
2. Some considerations have to be made:
  - a. It is the children’s aptitudes to use a toy in accordance with its destination which justify the choice to intend them for children or more or less than 3 years old; if this use can be gradual and start before three years to continue beyond, the toy has to be appropriate for the youngest children.
  - b. If a toy involves small parts that can be swallowed or inhaled or if there is a risk of strangulation, this does not mean, ipso facto, that the toy is intended for children of more than 3 years old.
  - c. Marking “is not appropriate for the children of less than 3 years old” (or of less than 36 months) cannot have as a justification the economic realization at the level of the tests and the setting in conformity of the products; it cannot therefore be found on a toy meeting the above criteria (for children less than 3 years) but which would present the risks for the children of less than 3 years old. (p. 3)
3. Soft toys, by their nature, are cuddly toys due to their light, soft, spongy and smooth qualities. Very young infants have indeed a natural instinct to cuddle and be cuddled. Soft toys normally appear as baby animals. These

are the kind of toys which attract very young infants and with which children instinctively identify. (p. 8)

KK. Trouble in Toyland: The 33<sup>rd</sup> Annual Survey of Toy Safety, 2018.

1. Our researchers identified Hatchimals Fabula Forest as a toy with potential choking hazards that is inappropriately labeled and marketed online. When Hatchimals eggs break open, the eggshell pieces fit the legal definition of “small parts.” The online listing on Walmart.com for the product did not have a choking hazard label, despite being marketed to children under 6 – [REDACTED]. (p. 10)

2. On Amazon, some models of both L.O.L. Surprise and Hatchimals are marketed to parents of children ages 2 and up (rather than 3 and up) meaning they can be found when a consumer searches for ages 2-4 under “Toys and Games.” [REDACTED]

3. CPSC Characteristics of Toys for Children Under Three.

The CPSC looks at whether toys are marketed to children under the age of three and whether the toys follow some general characteristics that make toys appealing to children under three, which are listed here:

Size and Weight: Small and light-weight, easy to handle.

Theme: Represents a common object found around the home, farm, or neighborhood.

Degree of Realism: Silly or cute, some realistic details.

Colors: Bright, contrasting colors covering large areas of the toy.

Action and Movement: May be silly, should be easy for child to cause movement. (p. 28)

LL. Reducing the Risk of Choking Hazards: Mouthing Behavior of Children Aged 1 Month to 5 Years, Injury Control and Safety Promotion, 2003.

Young children have a natural tendency to mouth items to explore their environment. Mouthing carries mechanical and chemical hazard potential for injury to the child, for example if they swallow an item they may choke. (p. 145)

Non-nutritive sucking (e.g., sucking on a dummy/pacifier) is thought to be adopted by infants as a response to frustration, or as a need for contact, or as a

part of the child's psychological development in exploring the world around them through touching and tasting objects with the mouth and tongue. (p. 145)

All items that are placed into a child's mouth have the potential to be a mechanical hazard. The most obvious hazards are choking or suffocation, although there is a risk of any item becoming stuck in the mouth and the resultant trauma may be serious. There is also the risk of foreign body incidents where a child swallows an item which may then cause harm to internal systems of the body. Some products, such as dummies/soothers, teething rings and bottle teats, are intended to be placed into the mouth. Unfortunately, products not intended to be mouthed invariably end up in children's mouths, as this is how young children explore their world. Obviously, child safety is of paramount concern, and so products must be as safe as possible for all forms of interaction, whether they are being handled or placed in the mouth. (p. 145)

Overall, mouthing generally shows little relationship with age. The results presented show that for overall mouthing (i.e., on all items including fingers) the highest estimated mean daily mouthing time on all items is for the 18-21 month age group (1:58:49, hours:minutes:seconds), and the lowest at age 4 (0:50:05). This is probably due to the wide variety of items mouthed, including clothes, fingers and thumbs. Dummy use does not show an obvious relationship with age. (p. 150)

Maximum estimated mouthing a dummy/soother is higher than on fingers for all ages except 5 year olds, but there is no real pattern of increase or decrease with age. (p. 151)

Anecdotal evidence from many parents taking part in this study indicated surprise at how much their child actually mouthed, and that they would have usually missed the short duration mouthing behaviors exhibited by their child. (p. 153)

- MM. An observational Study of Object Mouthing Behavior by Young Children, Pediatrics, 2001, p. 135.

Children mouth pacifiers significantly longer than other objects, regardless of age.

- NN. Small Parts Aspiration, Ingestion, and Choking in Small Children: Findings of the Small Parts Research Project, Risk Analysis, 1996.

While children less than 3 years old are most likely to mouth these objects, older children have experienced many incidents of injury or fatality due to mouthing the same objects. (p. 330)

- OO. Prevention and Management of Aerodigestive Foreign Body Injuries in Childhood, Pediatric Otolaryngology, 1996.

We now possess the potential for testing all items intended for use of young children prior to manufacturing the object. The modern world-wide economy creates manufacturing centers, often in the Pacific rim, that produce children's products, including toys, that are distributed worldwide. If a manufacturer produces several billion toys that have a design defect, it is only a matter of time before the risk is realized because the exposure is so great.

The reasonable approach is to prevent the manufacturing of these objects to protect children, to avoid liability to the manufacturer and the distributor, and to avoid the devastating economic loss that can occur to a family of a child who is needlessly or inadvertently injured or who dies from choking. (p. 1411)

- PP. Comments from The Toy Association, Inc. Regarding CPSC Draft Guidelines for Determining Age Appropriateness of Toys (2018), Docket No. CPSC-2018-0006.

A survey of parents' perceptions is referenced in which "most" parents reported that they consider the suggested age on toys as "only 'somewhat accurate'" – suggesting that manufacturers have to do better in this regard. (p. 2)

We do know from experience that parents and other adults often disregard or underemphasize an age grade in making their toy selections, most consider it "just a suggestion" (according to a 2017 Harris Poll, 82 percent think the age label on toy packaging is "just a suggestion"), and there is an oft-reported tendency towards choosing toys of a higher age grade for children who are deemed "more-advanced" in their parent's or caregiver's view (or in hopes to expedite learning and development). These factors provide evidence that parents may not fully understand the value and purpose of the age label on a package and that more information and outreach to consumers in this regard may be needed. (pp. 2 & 4)

- QQ. New National Survey Finds Parents Don't Always Follow Important Toy Safety Guidelines, 2018, p. 1.

A new national survey of toy-purchasing parents revealed some concerning behaviors involving their approach to toy safety. This survey, conducted by Wakefield Research on behalf of The Toy Association, found that 41 percent of parents don't always read the age label on a toy before purchasing it, and for those who do check, 94 percent admitted they still purchased a toy even when the age label indicated their child was too young to play with it.

The survey found that nearly all parents with multiple children (97 percent) have allowed their youngest child to play with a toy intended for their older sibling.

- RR. New National Survey Reveals Concerning Attitudes Toward Toy Safety, 11/1/17, p. 1.

A new national survey of toy-purchasing parents conducted online by Harris Poll on behalf of The Toy Association has revealed troublesome findings about parents' toy safety beliefs and behaviors.

81 percent of these parents say that when they shop for toys for children, they tend to focus more on the types of toys that kids are interested in, rather than the toys recommended for the child's age.

## **VII. Epoch Everlasting Play (EEP) Corporate and Calico Critters Product History**

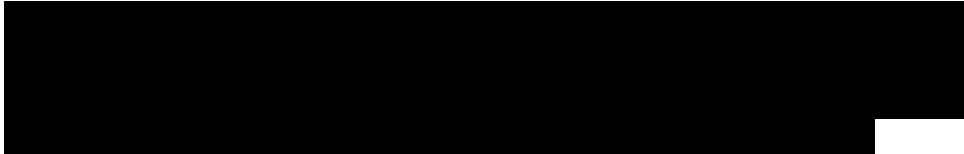
The following history of EEP and the Calico Critters product is based upon internet sources such as [www.calicocritters.com](http://www.calicocritters.com), Anna Vreeland deposition testimony, and discovery materials produced in this matter. Epoch Co. Ltd. is the creator of Calico Critters. According to the Calico Critters website ([www.calicocritters.com](http://www.calicocritters.com)), "Calico Critters is a line of miniature animal figures, with homes, furniture and accessories. The animal figures are unique because they are made of a special flocked material that gives them an endearing quality." Flocking is the process of depositing small fiber particles onto a surface to produce a velvety texture to increase tactile sensation. Established in 1958, Epoch Co. Ltd. is the third largest toy manufacturing company in Japan as of 2019. The Calico Critters line of miniature flocked animal figures was introduced in Japan in 1985 as Sylvanian Families and are distributed worldwide. In 1993, Tomy, who had been distributing the toys worldwide, lost the rights to the name Sylvanian Families in Canada and the USA. Tomy reintroduced the line under the new name Calico Critters of Cloverleaf Corners, now simply just called Calico Critters. In North America, the Calico Critters were released with different packaging. Tomy stopped selling Calico Critters, but a new company, International Playthings, LLC, picked up the line. International Playthings, LLC was sold to an affiliate of Epoch Company, Ltd. in November of 2008. International Playthings, LLC rebranded itself as Epoch Everlasting Play, LLC (EEP) in around February of 2017. Epoch Everlasting Play, LLC is a subsidiary of Epoch Co., Ltd., a global toy company based in Japan. Epoch Everlasting Play, LLC has a listed address in Parsippany, New Jersey. In 2018, sales of Calico Critters products in the U.S. and Canada exceeded \$65 million. The subject Calico Critters Yellow Labrador Twins and pacifier and bottle accessories product was purchased by Richaline Dedios at Walmart on 5/5/18. On or about 2019 after Dakotah Dedios's fatal incident, the pacifier and bottle accessories were replaced by a car accessory in the Calico Critters Yellow Labrador Twins product package. According to the [shop.epochsverlastingplay.com](http://shop.epochsverlastingplay.com) website accessed on 6/17/20, all the Calico Critters Twins products are shown with a toy car accessory instead of pacifier and bottle accessories.

## **VIII. Epoch Everlasting Play/Calico Critters/Sylvanian Families Background**

- A. Alyssa Masterson, Epoch Everlasting Play (EEP) director of marketing and strategic product development, testified at her deposition as the corporate representative. The following evidence is contained in the deposition of Alyssa Masterson and serves effectively as composite knowledge of the EEP corporation:

1. The parent organization is Epoch Company Ltd. of Tokyo, Japan. (p. 8)
2. Ms. Masterson has been designated to testify regarding subject matters F through Q and S in Exhibit 2. Ms. Masterson understands that her testimony on these particular issues is binding on the corporation. (pp. 12-13)
3. In 2019, Epoch Company Ltd. And Epoch Everlasting Play (EEP) stopped supplying the bottle and pacifier accessories with the Calico Critters Twins line of products. (p. 17)
4. Specifically, as to the Calico Critters Twins line of products, EEP does not have data and information on the development and design of those products. EEP does not maintain or request information regarding design or development of the products. (pp. 19-20)
5. Ms. Masterson does not know what is meant by postproduction and/or post sales surveillance. Ms. Masterson has never heard of post sales surveillance. (pp. 28-29)
6. EEP has a procedure to track incidents from consumers with regard to their product. EEP has a form and a procedure that is followed when they are notified of an incident with consumers. (p. 29)
7. EEP receives a report specifically from Walmart that gives information about reviews and comments on product listing pages. (p. 30)
8. EEP does not track Amazon reviews. (p. 31)
9. EEP has responded corporately to a customer issue on the Amazon website. The individuals who have access to that database would be within the customer service team. (p. 32)
10. Calicocritters.com is the brand website for Calico Critters and that website is managed by the parent organization as well as a third-party agency, CAI Media in Tokyo. Within EEP, Ms. Masterson is involved in overseeing the website. (p. 36)
11. Ms. Masterson is responsible for managing the person who oversees CPSC compliance. Ms. Masterson has no formal background, education, or training regarding CPSC compliance. Ms. Masterson has had the job to oversee product safety and CPSC compliance since February of 2020. (pp. 36-37)
12. Ms. Masterson is aware that the Calico Critters Yellow Labrador Twins are labelled as a choking hazard. (p. 38)



13. Ms. Masterson does not know the specifics of how the CPSC small parts cylinder testing is performed. (p. 39)
14. Ms. Masterson does not know how to define a small part under the CPSC regulations. (p. 39)
15. Ms. Masterson is aware of the ASTM F963-17 requirements, but she would not be able to recall verbatim what the ASTM F963-17 standard requirements are. (p. 41)
16. The Calico Critters line of products are flocked animals. EEP sells flocked animals. (pp. 42 & 49)
17. Ms. Masterson does not know if any of the Calico Critters products fit inside the small parts cylinder. (p. 44)
18. Ms. Masterson can see and agrees that the Labrador Twins fit completely within the small parts cylinder. Ms. Masterson agrees that the pacifier and bottle accessories fit completely within the small parts cylinder. (pp. 45-46)
19. Ms. Masterson did not know before her deposition that if a product fits inside the small parts cylinder, then that meets the definition of a small part under the CPSC. (p. 46)
20. Ms. Masterson is not familiar with Section 16 CFR 1501 of the CPSC regulation. (p. 46)
21. Ms. Masterson understands that a product is banned if the product contains a small part and it is intended for children under 3. Ms. Masterson understands that if the product is intended for children under 3, the product can't have small parts. (pp. 47-48)
22. 
23. Ms. Masterson does not know that flocked animals are banned if they fit inside the small parts cylinder. (pp. 49-50)
24. Identification of the U.S. importer or domestic manufacturer certifying compliance of the product is Epoch Everlasting Play, LLC. (p. 53)

25. Ms. Masterson does not know that Epoch Everlasting Play is the certifier of the Calico Critters line of products who is certifying compliance to the CPSC. (p. 53)
26. EEP has never age graded the Calico Critters toy line. Ms. Masterson does not know of anyone at the company that was qualified to perform age grading on the product. (pp. 54-56)
27. Ms. Masterson does not know if EEP has ever contracted with SGS to provide age grading evaluation on the Calico Critters line of products. (p. 61)
28. Ms. Masterson does not know whether SGS has ever performed any verification on the Calico Critters line of products to assure appropriate age grading. (p. 63)
29. Ms. Masterson does not know that in order to be a safe product for children, the age labeling on the product must be accurate and conform with CPSC regulations. (p. 63)
30. Ms. Masterson is aware that an importer manufacturer must comply with CPSC guidelines. (p. 64)
31. Ms. Masterson does not know as the supplier and distributor, EEP is responsible to assure that the products they are selling are appropriately age labeled. (pp. 64-65)
32. Ms. Masterson does not know that if a toy product is not appropriately age labeled, it presents a danger to children. (p. 65)
33. Ms. Masterson does not know that under the CPSC regulations if a toy is determined to be intended for use by children under 3, that the toy is subject to the small parts regulation of the Federal Hazardous Substances Act. (pp. 65-66)
34. Ms. Masterson does not know what a hazard analysis is and she does not know what a risk assessment is. Ms. Masterson does not know if EEP has ever performed a hazard analysis or risk assessment on the Calico Critters toy line. (p. 66)
35. Ms. Masterson does not know if EEP has any documentation that would indicate if and when a hazard analysis or risk assessment has been performed on the Calico Critters toy line and accessories. (pp. 66-67)
36. Ms. Masterson does not know if EEP maintains a database or documentation of any assessment or analysis that's ever been performed

- on the Calico Critters toy line relative to choking or aspiration issues. (p. 67)
37. Ms. Masterson does not know that it's foreseeable that a child could choke on the Calico Critters Twins bottle or pacifier accessory that's included with the Yellow Labrador Twins product. (p. 67)
  38. Ms. Masterson does not know that it's foreseeable that a child could mimic behavior and attempt to put a bottle or pacifier accessory in their mouth, thereby creating a choking hazard. (p. 68)
  39. Ms. Masterson does not know if EEP has ever advertised the Calico Critters product line for children under age 3. Ms. Masterson does not know if EEP has ever marketed the Calico Critters product line for children under age 3. Ms. Masterson does not know if EEP ever promoted or actively encouraged the Calico Critters product line as being suitable for children under age 3. (pp. 68-69)
  40. Ms. Masterson does not know if EEP were to market or promote the Calico Critters product line as being suitable for children under age 3, it certainly would be an indication from her company that the product stated intent is for children under age 3. (p. 69)
  41. Ms. Masterson is aware there are FAQs on the Calico Critters website. Exhibit 7 is the FAQ section of the website. The answer provided on the company website on 4/7/15 is that Calico Critters have small parts so they should only be given to children under 2 with adult supervision. Ms. Masterson does not know that the answer given by her company on their website tells parents asking that question that it is okay to give the Calico Critters toy to a child under 2 as long as they're supervised by an adult. (pp. 69-73)
  42. Ms. Masterson does not know that it is a violation of the Consumer Product Safety Act to issue a false certificate of conformity and could lead to civil penalty and possible criminal penalties under the CPSC. (pp. 73-74)
  43. Ms. Masterson does not know that as the importer and certifier, EEP is required to have a high degree of assurance that the Calico Critters product complies with all applicable children's product safety rules in order to lawfully certify through that certificate. (p. 74)
  44. Ms. Masterson does not know what undue influence training is under 16 CFR Section 11. Ms. Masterson does not know if EEP has ever provided its staff members training on undue influence under the CPSC. Ms. Masterson has never undergone any undue influence training. (pp. 74-75)

45. Information provided to Amazon is given by headquarters and manually inputted by EEP representatives. Copy is provided by Epoch Company, Ltd. EEP is responsible for getting information on the website through the portal. (pp. 75-76)
46. Epoch Company Ltd. is a manufacturer of the product. (p. 77)
47. The Calico Critters Yellow Labrador Twins product was changed by replacing the bottle and pacifier with a molded vehicle. No one ever discussed with Ms. Masterson why the change was made. (pp. 80-81)

- B. According to a news article from Farmington Mom, 911 Dispatcher hailed for Saving Choking Toddler, dated 7/4/13:

On 4/13/13, 22 month old James Rencher very nearly choked to death when a tiny plastic toy lodged in his windpipe at his home in Farmington, Utah. Although the paramedics could see the obstruction, they couldn't remove it. Doctors removed the obstruction at the hospital. Doctors told the child's mother there has been a brain trauma. At the hospital, the EMT brought out a specimen jar containing a toy pacifier, about one-third the size of a Cheerio, that was part of a Calico Critters toy set.

- C. According to the FAQs posted on the <https://calicocritters.com/parent/> website dated 7/29/14:

Q1. I want to buy my child Calico Critters. How old should she be to play with them?

Calico Critters have small parts so should only be given to children under 2 with adult supervision. Three years old is the best age to introduce Calico to your child, but maybe don't buy the sets with small accessories.

This FAQ remained on the Calico Critters website as of 4/12/19. As of 6/10/20, this FAQ was removed from the Calico Critters website.

- D. According to the Why Buy Calico Critters section on the <https://calicocritters.com/parent/> website dated 7/29/14:

Adorable new families and environments continue to be introduced every year, and Cloverleaf Corners remains a magical world of imagination for collectors of all ages.

This statement regarding collectors of all ages remains as of 6/10/20 on the Calico Critters website.

- E. According to the What are Calico Critters? section on the <https://calicocritters.com/parent/> website dated 7/29/14:

Calico Critters is a line of Miniature animal figures, with homes, furniture and accessories. The animal figures are unique because they are made of a special flocked material that gives them an endearing quality.

- F. According to the calicocritters.com website:

Dear Fans,

We are writing to you to inform that online activity of our Calico Critters Fan Club will no longer be available as of January 1, 2020.

With this notification, we want to inform you that Epoch Everlasting Play will no longer store or use your information and any personal data you have provided in connection with the Calico Critters Fan Club will be deleted.

Based on the calicocritters.com website information regarding the Calico Critters Fan Club, it appears that the Calico Critters Fan Club had access to personal data and information regarding Calico Critters consumers prior to the time Richaline Dedios purchased the subject Calico Critters Yellow Labrador Twins and accessories product.

As early as 2011, children were requested to enter their date of birth on the calicocritters.com website to register to join the Calico Critters Fan Club as shown in Figure 7. At the time the subject product was sold, EEP would have had knowledge of the ages of children interested in Calico Critters products based upon the Calico Critters Fan Club database.

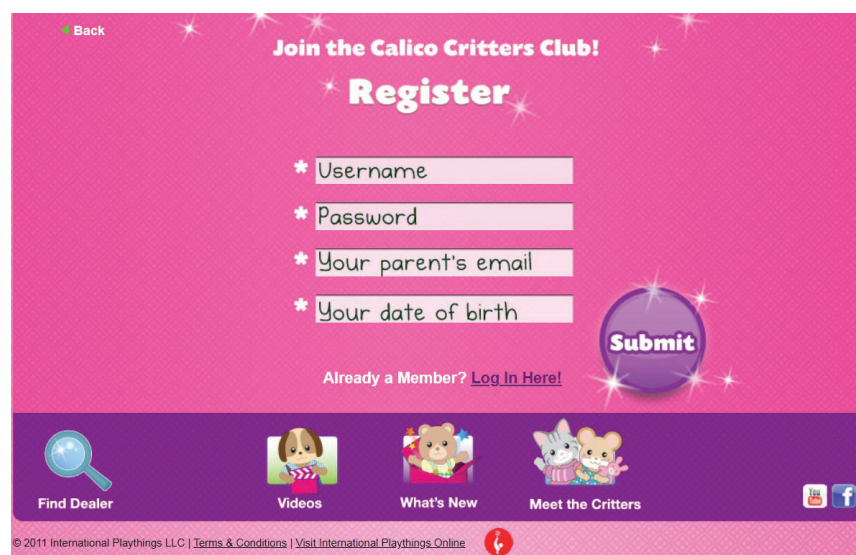


Figure 7. Calico Critters Fan Club Registration – Date of Birth Data Entry

- G. According to the Walmart website ([www.walmart.com](http://www.walmart.com)) accessed on 6/8/20, the specified age range for the Calico Critters Yellow Labrador Twins is 2 years as shown in Figure 8. The Walmart website product description states the figure toy set comes with a male and female dog made from flocked plastic. There is no mention of accessories with this product description. The product image on the Walmart website shows two dogs with a bottle accessory, but the product image does not show the pacifier accessory as displayed in Figure 9. The Walmart website also includes 2 year olds in the age range for the following Calico Critters: Hopscotch Rabbit Twins, Fluffy Hamster Twins, Sandy Cat Twins, Comfy Living Room Set Furniture Accessories, and Deluxe Kozy Kitchen Set.

#### Specifications

Brand	Calico Critters
Age Range	2 years
Assembled Product Weight	0.9 lbs
Assembled Product Dimensions (L x W x H)	8.00 x 8.00 x 6.00 Inches

Figure 8. Walmart.com Calico Critters Yellow Labrador Twins Specs (Age Range 2 Years)- 6/8/20



Figure 9. Walmart.com Calico Critters Yellow Labrador Twins Product Image – No Pacifier Accessory Shown

- H. Figure 10 shows a photographic chronology of the Calico Critters Yellow Labrador Twins product package based upon SGS test reports. In 2012, the Calico Critters Yellow Labrador Twins product package contained clear cellophane on the top such that the pacifier and bottle accessories were visible from multiple perspectives as shown in the left image in Figure 10. From 2016 through 2018, the Calico Critters Yellow Labrador Twins package was changed where the clear cellophane on the top was replaced by opaque cardboard such that the pacifier and bottle accessories are not visible from the perspective taken in the SGS report photographs. The toy car accessory is visible in the 2019 Calico Critters Yellow Labrador Twins product package shown in the SGS test report photograph.



Figure 10. Calico Critters Yellow Labrador Twins Package History–SGS Reports

Figure 11 shows a front view of a Calico Critters Yellow Labrador Twins package from worthpoint.com, with the package similar to the 2012 package displayed in Figure 10, where the pacifier and bottle accessories are clearly visible.



Figure 11. Calico Critters Yellow Labrador Twins Package – Worthpoint.com

- I. In circa 2010, the Sylvanian Families Golden Labrador Twins package was labeled 4+ as shown in Figure 12. The package insert does not have a cavity above the Golden Labrador Twins heads and the pacifier and bottle accessories locations are clearly visible within the package. According to the Gumtree.com sales description of the same product, the dummy (pacifier) is missing.



Figure 12. Sylvanian Families Golden Labrador Twins – 4+ Label

- J. Sylvanian Families Dormice Twins packaging has also been labeled 4+ as shown in Figure 13. Also, the pacifier and bottle accessories are clearly visible in Figure 13 due to the shape of the package insert and the positioning of these accessories within the package. It should be noted that the package insert contains a cavity above the dormice twins' heads to accommodate the ears of these flocked animal figures.





Figure 13. Sylvanian Families Dormice Twins Package Label – 4+ Label

- K. According to the amazon.com website, the manufacturer’s recommended age for the Calico Critters Yellow Labrador dog family Twins 6 figure set is 4 years and up.
- L. Figure 14 shows the Calico Critters Lambrook Twins where the pacifier and bottle accessories are clearly visible due to the clear cellophane at the top of the package and the placement of these accessories on the package insert.



Figure 14. Calico Critters Lambrook Twins – Pacifier & Bottle Accessories Visible

- M. Figure 15 shows a brand new Sylvanian Families individual polar bear figure with ice cream cone accessory sold in a clear blister pack without an age grade or warning on the package.



Figure 15. Sylvanian Families Individual Polar Bear Figure with Ice Cream Cone Accessory – No Age Grade or Warning Label

- N. Figure 16 shows the Calico Critters Yellow Labrador Family package containing no accessories.



Figure 16. Calico Critters Yellow Labrador Family Package - No Accessories Included

- O. BNIB Calico Critters Yellow Labrador Family and Yellow Labrador Twins, eBay.

Figure 17 shows a photograph from the eBay website for a Calico Critters Yellow Labrador Twins 6 figure set where no accessories are visible and there is no reference to accessories on the package.



Figure 17. CC Yellow Labrador Twins 6 Figure Set – eBay Website Photo

- P. Figure 18 shows the Calico Critters Ellwoods Elephant Twins package without accessories.



Figure 18. Calico Critters Ellwoods Elephant Twins – No Accessories Included

- Q. According to [www.sylvanianstorekeepers.com](http://www.sylvanianstorekeepers.com) dated 3/3/18 and ebay.co.uk, the Sylvanian Families Golden Labrador Baby product (circa 2010) was labeled as 4+ and was sold with a crib accessory instead of a pacifier accessory as shown in Figure 19. The crib accessory is larger than the Golden Labrador Baby and the bottle accessory.



Figure 19. Sylvanian Families Golden Labrador Baby – Sold with Crib Accessory

- R. The package shown in Figure 20 for the Japanese version of the Sylvanian Families Yellow Labrador Twins circa 2017 sold on eBay has the pacifier and bottle accessories clearly visible due to the left (girl) flocked animal figure being positioned lower in the package than the boy on the right.



Figure 20. Sylvanian Families Yellow Labrador Twins Japanese Version – Left (Girl) Figure Positioned Lower Than Right (Boy) Figure

- S. Figure 21 shows a Calico Critters multi-piece accessories set that contains two bottles and two pacifiers.



Figure 21. Calico Critters Accessories Set – 2 Pacifiers & 2 Bottles Included

- T. Figure 22 shows another Calico Critters multi-piece accessories set that contains two bottles and two pacifiers.



Figure 22. Calico Critters Accessories Set – 2 Pacifiers & 2 Bottles Included

- U. Figure 23 depicts a Calico Critters Baby Nursery Set that contains over 20 accessories. This set is sold on the [epocheverlastingplay.com](http://epocheverlastingplay.com) website.



Figure 23. Calico Critters Baby Nursery Accessories Set

- U. The following customer reviews for the Calico Critters Yellow Labrador Twins appear on the amazon.com website:
1. Customers stated that the bottle and pacifier accessories did not stay in the Calico Critters mouth.
  2. Customers stated that the bottle and pacifier accessories are tiny and became lost.
  3. Customers stated that their order was missing the accessories.
  4. A customer stated the Calico Critters are supposed to have a bottle and pacifier and they do not have those.
  5. Customers stated they bought the Calico Critters for the following ages: 2 year old (9/12/17, 3/13/18) and 2.5 years old (3/17/16).
  6. Customers stated that the pacifier and bottle accessories are tiny.
- V. Best Calico Critter Toys in 2020 (Review & Guide, Reviews The Beast.
- Babies under the age of 3 can also play with Calico Critters but under strict adult supervision.
- W. Calico Critters – Good for a 4 Year Old?, 7/1/12.
- I think the best age is somewhere between 2 and 7.
- X. Calico Critters in Raleigh, Chapel Hill, Cary, Learning Express Gifts.
- Calico Critters have small parts so they should only be given to children under 2 with adult supervision.
- Y. Figure 24 shows a graph from [www.fatbraintoys.com](http://www.fatbraintoys.com) which displays age appropriateness for Calico Critters Baby Castle Playground where 17% of the recipients were classified as babies under 3 years of age. The orange color in the chart indicates ages that are less than the manufacturer's suggested age according to the [www.fatbraintoys.com](http://www.fatbraintoys.com) website.

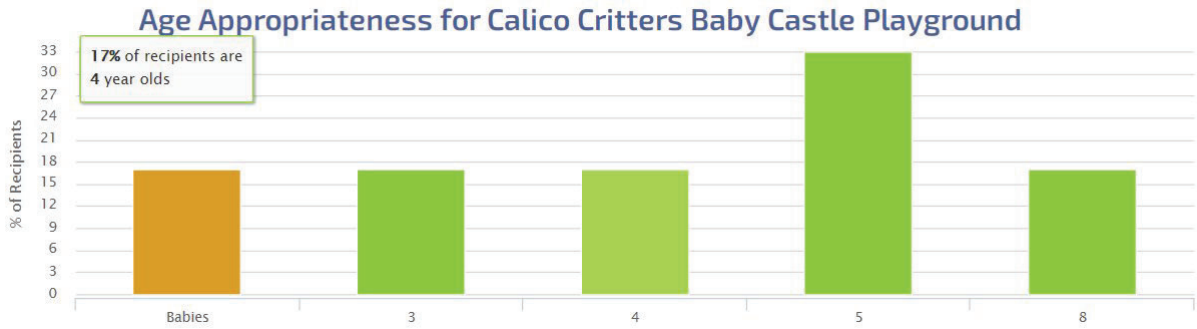


Figure 24. Age Appropriateness for Calico Critters Baby Castle Playground

- Z. Calico Critters Cloverleaf Townhome Gift Set, AnnMarie John: A Travel & Lifestyle Blog, 2014.

I must admit that I did need adult supervision because while I am not quite 3, the parts are tiny and I still have a habit of putting things in my mouth. I did however enjoy playing with my Calico Critters Cloverleaf Townhome Gift Set and I know that your little ones will too. This totally gets my TWO TINY THUMBS UP! Figure 25 shows 2 year old Madison playing with the Calico Critters Cloverleaf Townhome Gift Set in 2014.



Figure 25. 2 Year Old Madison Playing with Calico Critters in 2014

- AA. Squinkies and Calico Critters – Two Hot Toys, Two Choking Hazards, Echo Flam, 2010.

Squinkies and Calico Critters both pose health problems to small children, yet they are marketed to a much younger crowd. (p. 1)

The Calico Critters website is no different. There are links to coloring pages, stories and interactive games. One interactive game allows the user to place stickers on a Calico Critter home. Both websites offer games aimed at a very



young consumer, but the toys are tiny and not suitable for the age group being targeted. (p. 2)

The Calico Critters themselves are small enough to choke a child of 36 months and the accessories with some of the toys are even smaller. (p. 2)

Choking hazards for Squinkies and Calico Critters is not easily found on the official websites. (p. 3)

The trouble facing parents is marketing verses the manufacturer's suggestions. Marketing is clearly aimed for the youngest crowd, but the toys are too small for the age group who will be most pulled into the hottest toys of Christmas 2010 craze. Parents need to leave the hottest toys of Christmas 2010 to older children this year. Marketing to the masses is a money making business with potentially harmful risks. (p. 3)

BB. Are Sylvanian Families Suitable for a 2 Year Old?, Mumsnet.

My 2yo dd loves them. (16 Mar 12)

We got some for dd2 at Christmas when she was just 2. (16 Mar 12)

DD1 got a some for her 2<sup>nd</sup> birthday – we kept all the fiddly bits (usually separately packaged) away from her. (17 Mar 12)

CC. The Best Toys for 2-Year-Olds 2020.

Calico Critters Cozy Cottage: At 2 and 3, toddlers are often pretending to be Mommy or Daddy and working through ideas about separation. This one features little animal critters.

DD. Very Best Toys for Toddlers: 2 and Up, Chronicles of a Babywise Mom, 7/19/09.

This post is for 2 and up. So the toys might be great for your two year old, also, and can also be great for your three year old.

Calico Critters: For Kaitlyn's birthday, my parents got her some Calico Critters. She really likes them.

EE. Calico Critters, www.reddit.com, 2016.

My daughter (20 months) has fallen in love with Calico Critters.

FF. Calico Critters Review Site, calicocritters.org.

The Calico Critters range is known for the quality of construction and attention to detail. Each small figure has a movable head and is covered with a plush surface.

The figures are suitable for ages four and above.

- GG. Toddler Favorites for the Holidays: Calico Critters Luxury Townhouse Giveaway Ends 12/13, 2015.

Let me say first off that I believe these are meant for children ages 5 or older. The accessories are very small. Chelsea still occasionally puts things in her mouth.

- HH. Where do you Start with the Sylvanian Family Range, Netmums, 2014.

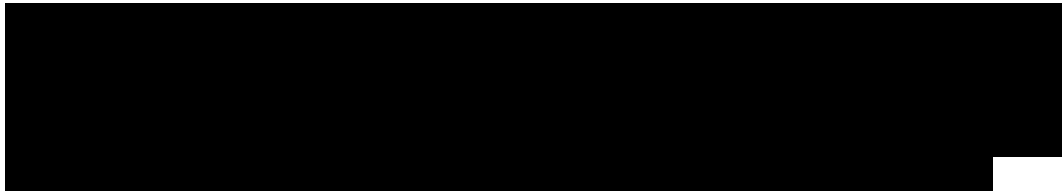
I was thinking of getting my 2 year old the Sylvanian Family range (she's 3 in feb) because she likes all those figure type playsets.

- II. From 2003 through 2012, the U.S. CPSC in cooperation with International Playthings announced a voluntary recall of seven products due to small parts choking hazards. EEP, formerly International Playthings, knew or should have known of the following CPSC recall history of former children's products associated with small parts choking hazards:

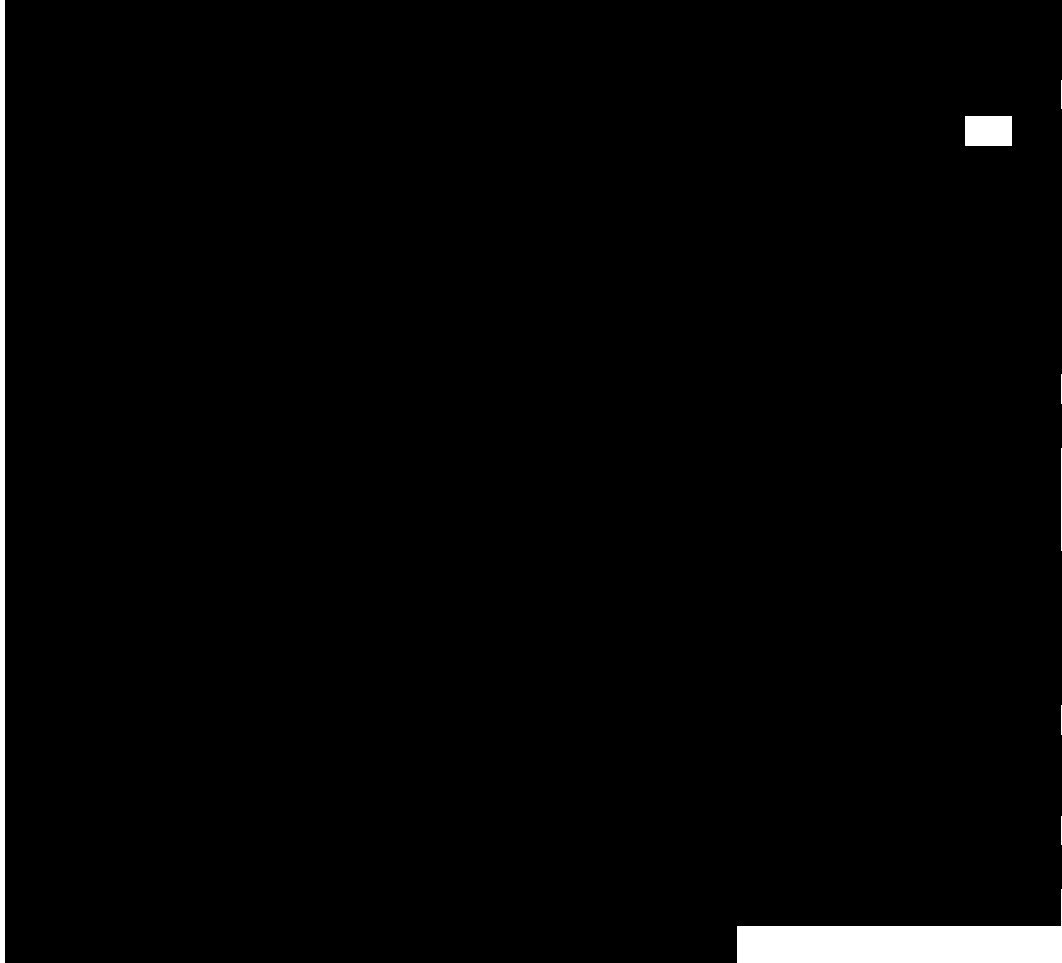
1. International Playthings received three reports of small parts detaching from Earlyears Bobbie Bear Stacking Rings, posing a choking hazard to young children. (Release #03-165, 7/31/03)
2. The spiral section of the Earlyears Spirolly Rattle can come apart, releasing small balls inside that can pose a choking hazard to young children. (Release #05-024, 10/21/04)
3. Small parts can detach from Flexitoys Monster-Size Vehicles, which pose a choking hazard to young children. (Release #06-034, 11/22/05)
4. The heads on the figures sold with the Viking Chubbies Toy Cars can detach, posing a choking hazard to young children. (Release #06-033, 11/22/05)
5. The iPlay My First Mobile Phone tallow antenna can detach, posing a choking hazard to young children. (Release #06-099, 2/28/06)
6. International Playthings received three reports of the shiny material detaching from the Taggies Strollin' Along Stroller Activity Bar elephant's ear and children putting it in their mouth. (Release #08-373, 8/26/08)
7. The Tumblekins Toys can break into small pieces with sharp points, posing choking and lacerations hazards to children. (Release #12-111, 2/16/12)

**IX. Safety Analysis**

- A. Prior to Richaline Dedios purchasing the subject Calico Critters Yellow Labrador Twins and accessories product at Walmart, it was reasonably foreseeable to Epoch Company, Ltd. (manufacturer), EEP (supplier), and Walmart (retailer) that children under 3 years old would be using these flocked animal figures and pacifier and bottle accessories. This opinion is based upon information contained on the Calico Critters website (collectors of all ages and given to children under 2), Calico Critters Fan Club, Walmart website (age range 2 years), Amazon website, internet consumer blogs, bottle and pacifier accessories included with the product, 16 CFR Part 1501.2, ASTM F963-17, The Toy Association surveys, child toy choking incident statistics, fatbraintoy.com age graph, Learning Express website, toy websites that reiterate the FAQ information from the Calico Critters website, Echo Flam article, toy age determination guidelines, U.S. CPSC documents (1501.2 list of definitely covered products intended for infants and toddlers under 3 years of age), 22 month old James Rencher's Calico Critters toy pacifier choking incident in 2013, Federal Register (1501.2 included a lengthy list of products that are definitely covered), and CPSC staff's retail survey of toys.
- B. Prior to Richaline Dedios purchasing the subject Calico Critters Yellow Labrador Twins and accessories product at Walmart, Epoch Company, Ltd., EEP, and Walmart knew or should have known that the Yellow Labrador Twins and the pacifier and bottle accessories presented a small parts choking hazard to children under 3 years of age. This opinion is based upon Ms. Masterson's deposition testimony binding the EEP company knowledge, the warnings on the subject toy package, the Yellow Labrador Twins and the pacifier and bottle accessories fit entirely within the small parts cylinder, 22 month old James Rencher's Calico Critters toy pacifier choking incident in 2013, Calico Critters retailer websites (including Walmart), Federal Register, U.S. CPSC documents, toy age determination guidelines, Calico Critters website, 16 CFR 1501.2, ASTM F963-17, toy medical literature, child toy choking incident statistics, child mouthing literature, internet consumer blogs, the tiny pacifier and bottle accessories do not remain in the flocked animal figure's mouth and can get easily lost, and bottles and pacifiers are generally items that children under age 3 put in their mouth. Children under 3 years of age, who by virtue of their young age are known to mouth objects are subject to a small parts choking hazard associated with the subject Calico Critters Yellow Labrador Twins and the pacifier and bottle accessories.

C. 

D.

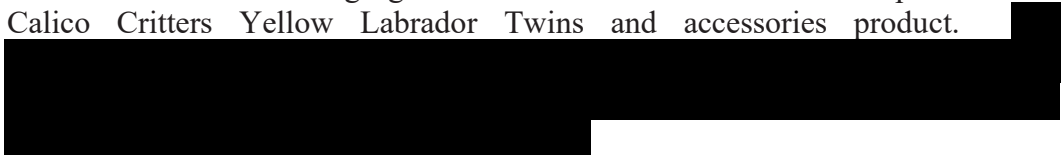


E.




Ms. Masterson testified that EEP has never age graded the Calico Critters toy line, and she does not know of anyone at the company that was qualified to perform age grading on the product. Calico Critters and Sylvania Families (including Golden Labrador Twins) have been labeled, marketed, advertised, and promoted throughout the world by the defendants for children ages 1, 2, 3, and 4. There is no consistency or consensus from Epoch Company, Ltd., EEP, and its retail

partners such as Walmart regarding age grading of the Calico Critters. Based upon the safety research previously cited in this report, including The Toy Industry polls, parents reported that the age marking on the package to be a suggestion that is only somewhat accurate. According to a 2017 Harris Poll, 82 percent think the age label on toy packaging is “just a suggestion.” A poll conducted on behalf of the Toy Industry indicated that 94 percent of toy purchasers admitted they ignored the age grade suggestion on the toy package. Dakotah Dedios was over 33 months old at the time of her death, less than 3 months shy of the 3+ age indicated on the subject toy package. Given the child mouthing behavior research presented in this report, a child generally does not completely stop mouthing objects when reaching 36 months of age. The defendants knew or should have known that children in the labeled, marketed, advertised, and promoted age range of 1 to 4 years old generally have a tendency to mouth toy objects, especially when it is a pacifier and a bottle that frequently go in the mouth of a child less than 3 years old. According to the child mouthing research presented in this report, a pacifier is the most popular object to mouth for a child in the 1 to 4 age range. Given that both Calico Critters and Sylvanian Families product packages have been previously labeled 4+ (including the Golden Labrador Twins), even the manufacturer and supplier indicate that Calico Critters are not reasonably safe for 3 year olds, which is a further contradiction to the Calico Critters website FAQs (children less than 2 years old) and an indication that Calico Critters are intended for children of all ages. Further, this 4+ age grade previously provided on packages for Calico Critters and Sylvanian Families is inconsistent with the age grade of 3+ listed on the SGS test reports for the Calico Critters Yellow Labrador Twins and accessories product.



- F. Prior to Richaline Dedios purchasing the subject Calico Critters Yellow Labrador Twins product at Walmart, the defendants failed to properly apply the hazard control hierarchy (safety hierarchy) to achieve an acceptable level of risk associated with the product by eliminating the small parts choking hazard. The author published a peer-reviewed paper entitled “Safety Hierarchy” in the National Safety Council Journal of Safety Research in 1986, approximately at the same time that the Calico Critters line of miniature flocked animal figures was introduced in Japan in 1985 as Sylvanian Families and were distributed worldwide. Various versions of the hazard control hierarchy (safety hierarchy) are presented in this report. The first priority of the safety hierarchy is to eliminate the hazard and/or likelihood of encountering the hazard. Substitution is a form of hazard elimination. The defendants have demonstrated after Dakotah Dedios’s incident and death that the pacifier and bottle accessories that fit entirely within the small parts cylinder can be eliminated from the Calico Critters Yellow Labrador product and substituted with a different larger car accessory that does not fit entirely within the small parts cylinder. Also, prior to the sale of the subject product in 2018, there was a Sylvanian Families Golden Labrador Baby

product sold circa 2010 with a crib accessory instead of a pacifier accessory. Based upon Figure 19, it appears that the crib accessory would not fit entirely in the small parts cylinder. In addition, there are other Calico Critters, including flocked animal figure Twins and the Yellow Labrador Family, that do not contain accessories. Eliminating the tiny bottle and pacifier accessories from the Calico Critters Yellow Labrador Twins product would also eliminate the small parts choking hazard associated with these accessories. According to the U.S. CPSC, frequently the necessary adjustments will involve little more than removing a small part which does not change the fundamental nature of the toy. It is feasible to supply the Calico Critters accessories in a separate package as previously stated in this report. In fact, Calico Critters accessories sets (including bottles and pacifiers) were sold separately from the flocked animal figures prior to the sale of the subject product.



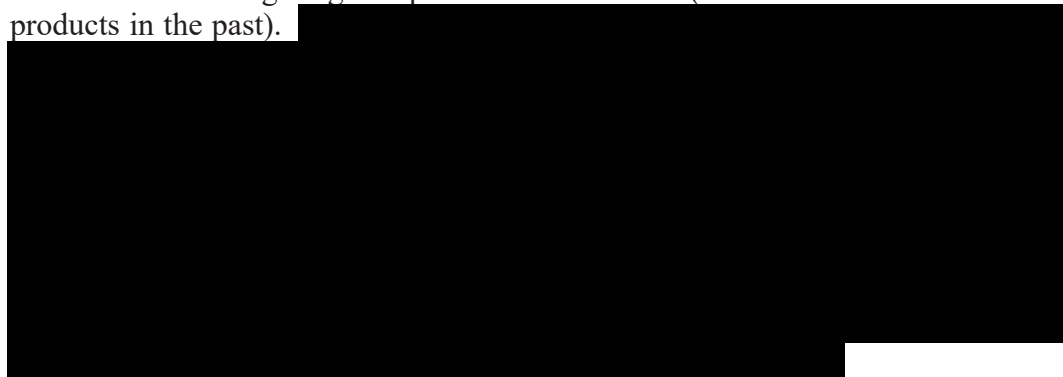
Warnings are the third priority of the safety hierarchy. The warnings on the subject Calico Critters Yellow Labrador Twins package do not adequately alert the purchaser that there are tiny accessories that pose a small parts choking hazard, especially given that the subject package obscures viewing the pacifier and bottle accessories (as shown in the SGS test report photographs, ESi exemplar photographs, and internet retailer photographs). A consumer may be misled into believing that there are no accessories in this package given there are Calico Critters flocked animal figure pairs and Yellow Labrador Family figure sets that do not contain accessories. The principal display panel of the subject product only identifies the Calico Critters Yellow Labrador Twins, not the pacifier and bottle accessories. Further, the Calico Critters Yellow Labrador Twins animal figures themselves pose a small parts choking hazard because they fit entirely within the small parts cylinder. The exemplar Calico Critters Yellow Labrador Twins package references boy Twin Marley taking out his trumpet and pretending to play a song with his sister. However, there are pacifier and bottle accessories, instead of a trumpet accessory, contained within the package.

The exemplar Calico Critters Yellow Labrador Twins package indicates that Calico Critters is a line of beautifully detailed animal figures, houses, furniture, and accessories. The subject toy purchaser can easily get confused and misled as to whether the Calico Critters package contains accessories. Potential points of confusion are due to inconsistencies in:

- the exterior and interior packaging design characteristics, including opacity and contents positioning.
- improper labeling as to which accessories the package contains (if any) as some products are intended to have accessories (Twins) and some do not (Families). The back of the subject package references a toy trumpet for boy twin Marley.
- is the package missing accessories as reported by consumer internet reviews and comments.

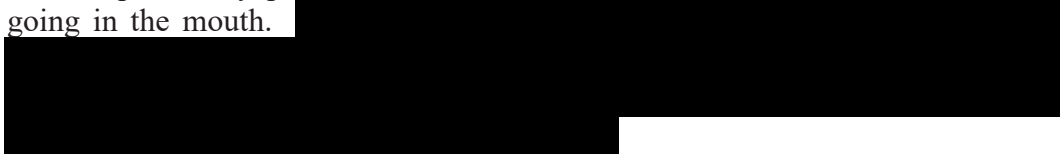
- whether the Calico Critters or the accessories (or both) pose a small parts choking hazard (in this case, both the Yellow Labrador Twins and the bottle and pacifier accessories fit entirely within the small parts cylinder).
- does the package contain accessories that differ from the product's marketing, advertising, and promotion and package labeling (especially during the transition phase from the bottle and pacifier accessories to the toy car accessories associated with the Yellow Labrador Twins product following Dakotah Dedios's death).
- how many accessories are supposed to be included in the package (some internet marketing such as Walmart.com shows a bottle accessory and not the pacifier accessory).

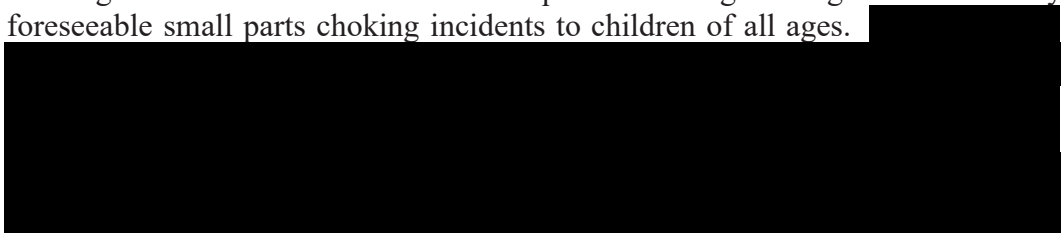
The defendants should have been more transparent and specific regarding the product contents inside the package. They should have provided adequate warnings regarding the presence of the bottle accessory and the pacifier accessory within the package and the small parts choking hazard associated with these specific accessories. This is especially critical as they marketed, advertised, and promoted the Calico Critters towards children of all ages including under age 2 (1 year old). Had the packaging been adequately labeled with the safety information that there was a potential small parts choking hazard with not only the Twins but also the pacifier and bottle accessories, that would have provided an opportunity for a consumer purchaser like Richaline Dedios to remove the small parts accessories before giving the product to her child (as she had done with other products in the past).



- G. The packaging associated with the subject Calico Critters Yellow Labrador Twins was not adequately designed because the bottle and pacifier accessories are not clearly visible in all viewing orientations of the product, as shown in the SGS test report photographs, ESi exemplar photographs, and internet retailer photographs. The presence of the bottle and pacifier accessories in the package is not open and obvious to the purchaser. In 2012, approximately six years prior to Richaline Dedios purchasing the subject Calico Critters Yellow Labrador Twins and accessories product at Walmart, the previous package design contained clear cellophane on the top such that the pacifier and bottle accessories were visible from multiple perspectives. In addition, other Calico Critters and Sylvanian Families Animal Twins products (including Yellow Labrador Twins) contained a different package insert design such that the pacifier and bottle accessories are positioned lower within the package to improve their visibility. The subject

product package insert has cavities above the Yellow Labrador Twins heads. These cavities are consistent with Calico Critters flocked animal figures with large ears that stand up on top of the head. Figures 10-12 show that there was not a product package insert cavity above the Calico Critters Yellow/Golden Labrador Twins heads before and after the subject product was sold in 2018. Also, Figure 11 shows there is not an insert included in the Calico Critters Yellow Labrador Twins package sold before 2018 and the bottle and pacifier accessories are clearly visible and attached to the back of the cardboard package. It should be noted that when the pacifier and bottle accessories were replaced by the toy car accessory following Dakotah Dedios's death, the car accessory was clearly visible and positioned at the bottom of the package, instead of the accessories being positioned at the top of the subject package. Also, the subject package is not adequately labeled in a reasonable manner to clearly identify the subject bottle and pacifier accessories contained within the package and the small parts choking hazard specifically posed by these tiny accessories which have the purpose of going in the mouth.



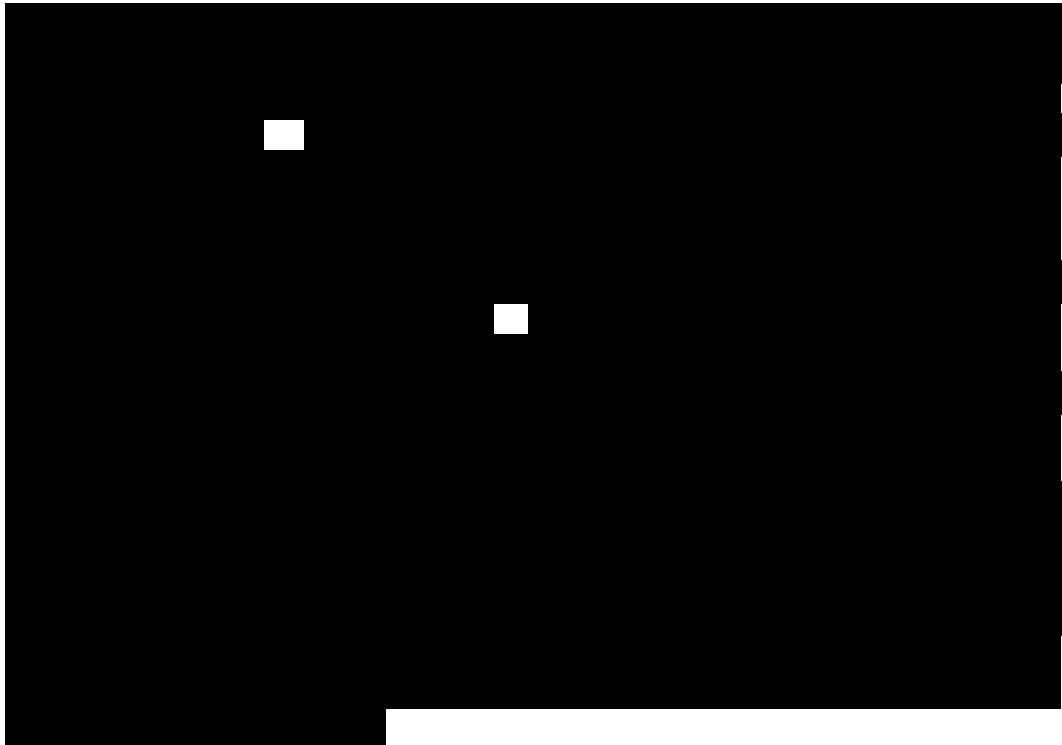
- H. At the time of sale of the subject Calico Critters Yellow Labrador Twins and accessories, the product was defective in design and unreasonably dangerous because the reasonably foreseeable risks of harm posed by the product associated with the small parts choking hazard could have been reduced or avoided by the adoption of reasonable alternative designs.
  - I. Prior to 2018, there were several other technologically, economically, and functionally feasible safer alternative designs which eliminate the subject small parts choking hazard associated with the subject Calico Critters Yellow Labrador Twins and pacifier and bottle accessories. These safer alternative designs would have most likely prevented Dakotah Dedios's incident and death without substantially impairing the product's utility, and were economically and technologically feasible at the time the product left the control of the manufacturer and supplier by the application of existing or reasonably achievable scientific knowledge.
  - J. At the time of sale of the subject Calico Critters Yellow Labrador Twins and accessories, the product was defective because there was a failure to provide warnings or instructions that are adequate to safeguard against reasonably foreseeable small parts choking incidents to children of all ages.
- 





- K. At the time of sale of the subject Calico Critters Yellow Labrador Twins and accessories, the product was placed on the market and posed an unreasonable risk of injury to users.
- L. At the time of sale of the subject Calico Critters Yellow Labrador Twins and accessories, the product was defectively designed and unreasonably dangerous.
- M. The retail cost of the Calico Critters Yellow Labrador Twins and accessories product can reach \$11 or more. Consumers have stated in internet postings that the cost of the Calico Critters is generally high. The relative cost of incorporating alternative product designs, packaging, and warnings with respect to the subject product was economically feasible and would not have significantly affected the utility of the product. In fact, removing the bottle and pacifier accessories entirely from the Calico Critters Yellow Labrador Twins product, similar to the Calico Critters Yellow Labrador Family product sold without accessories in the package, would decrease the manufacturing cost of the product.

N.



- O. The defective and unreasonably dangerous condition of the subject Calico Critters Yellow Labrador Twins and accessories product as designed, manufactured, supplied, and sold by the defendants proximately caused Dakotah Dedios's incident and death.

- P. The negligent conduct of the defendants in designing, manufacturing, supplying, and selling the subject Calico Critters Yellow Labrador Twins and accessories product in a defective and unreasonably dangerous condition proximately caused Dakotah Dedios's incident and death.
- Q. At the time of sale of the subject Calico Critters Yellow Labrador Twins and accessories, the defendants were negligent because they manufactured, supplied, and sold a defective and unreasonably dangerous product that did not meet applicable toy safety regulations, standards, and guidelines and created an unreasonable risk of harm due to a small parts choking hazard for an [REDACTED] vulnerable child user under the age of 3. Indeed, ASTM F963-17, section 4.20.2, specifically states that toy pacifiers attached to, or sold with, toys intended for children under 36 months of age shall comply with the requirements outlined in 4.6.1 of this specification (small objects). The deposition testimony of Ms. Masterson, as the EEP corporate representative, indicates the company's complete lack of safety awareness associated with the subject toy design, packaging, marketing, promoting, advertising, applicable safety regulations and standards, toy industry research, U.S. CPSC requirements, small parts cylinder test, and the like. EEP continued to sell remaining inventory of the subject Yellow Labrador Twins with the bottle and pacifier accessories even after the decision was made to substitute the larger car accessory that does not fit entirely within the small parts cylinder. At the time of issuance of this report, the Calico Critters Yellow Labrador Twins product with the pacifier and bottle accessories is still available for sale on the internet, including at Walmart.com. There have been seven product recalls associated with small parts choking hazards announced by the U.S. CPSC in cooperation with International Playthings from 2003 through 2012, in addition to the 4/13/13 incident in Farmington, Utah where 22 month old James Rencher very nearly choked to death when a tiny Calico Critters plastic toy pacifier (similar to the subject pacifier accessory) lodged in his windpipe. Based upon these and the totality of the evidence presented in this report, the defendants did not take adequate steps to act in the manner of a reasonable manufacturer, supplier, and retailer of a toy [REDACTED].
- [REDACTED] According to the Federal Register, "close calls" are important indicators that a risk of injury from small parts exist. The Commission believes that it should not wait for deaths, injuries, or even "close calls" to occur before determining that a children's product presents an unreasonable risk of injury under the FHSA.
- R. There is no evidence that the defendants conducted proper market surveillance for relevant incidents. EEP corporate representative Ms. Masterson testified that she does not know what is meant by postproduction and/or post sales surveillance. According to U.S. CPSC official agency guidance on best practices (www.cpsc.gov), ISO 10377:2013, ISO 10393:2013, and ISO/IEC Guide 50-2014, the defendants have a responsibility to conduct market surveillance. Had they done so, they would have identified the "close call" incident in 2013 involving 22 month old James Rencher with the near-fatal similar scenario

involving the same Calico Critters small parts pacifier accessory in the mouth of a child under 3 years old. ESI was able to identify this prior incident during its market surveillance research by simply performing a Google search using the keywords “Calico Critters choking incidents,” as shown in Figure 26. According to the Federal Register, “close calls” are important indicators that a risk of injury from small parts exist. Given that the defendants took action and made design changes to the subject product accessories following Dakotah Dedios’s fatal incident, it follows that they should have implemented the same design changes had they identified this previous incident information at that time. Had the defendants done so and eliminated the small parts choking hazard pacifier accessory at that time, Dakotah Dedios’s fatal incident most likely would not have occurred. In fact, Sylvanian Families Golden Labrador flocked animal baby figures were sold with a crib accessory that appears to not fit entirely in the small parts cylinder, instead of a tiny pacifier accessory that does fit entirely in the small parts cylinder, years before the subject product was sold.

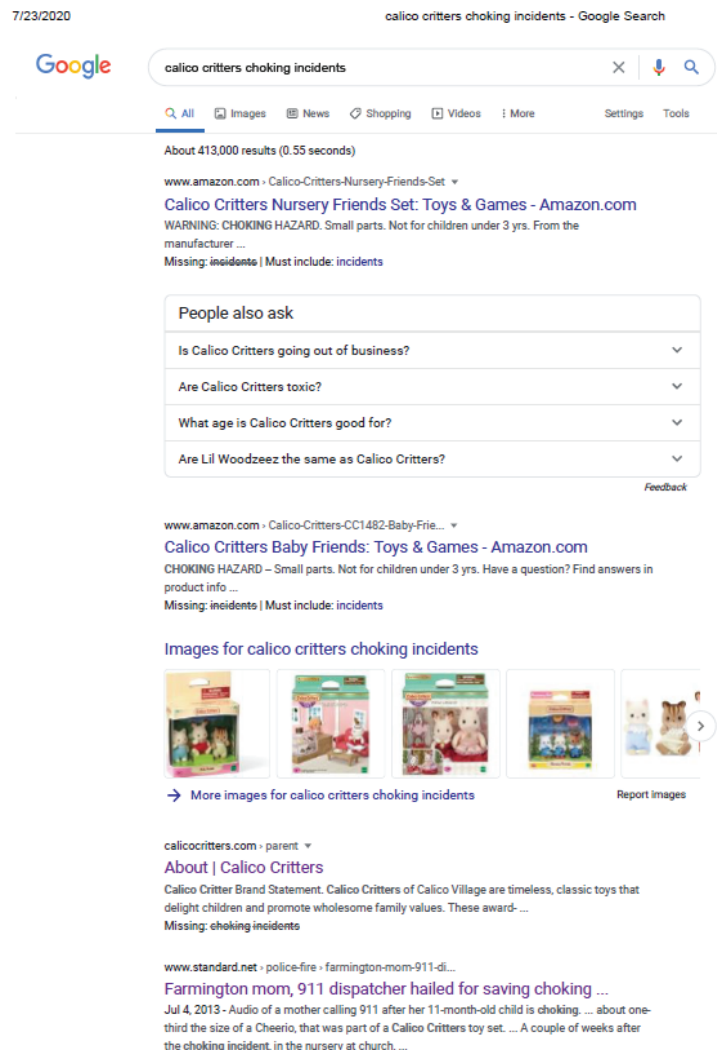
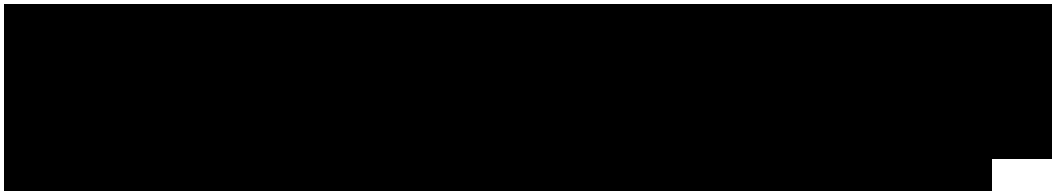


Figure 26. “Calico Critters Choking Incidents” Google Search

**X. Summary of Opinions**

A. At the time the subject Calico Critters Yellow Labrador Twins and accessories product was sold to Richaline Dedios at Walmart, it was reasonably foreseeable to Epoch Company, Ltd., EEP, and Walmart that children under 3 years old would be using these flocked animal figures and pacifier and bottle accessories.

B. At the time the subject Calico Critters Yellow Labrador Twins and accessories product was sold to Richaline Dedios at Walmart, the defendants knew or should have known that the Yellow Labrador Twins and the pacifier and bottle accessories presented a small parts choking hazard to children under 3 years of age. EEP corporate representative Ms. Masterson testified that she is aware that the Calico Critters Yellow Labrador Twins are labelled as a choking hazard. Ms. Masterson also testified that she can see and agrees that the Yellow Labrador Twins and the pacifier and bottle accessories fit entirely within the small parts cylinder.

C. 

D. 

E. The packaging associated with the subject Calico Critters Yellow Labrador Twins and accessories product was not adequately designed because the bottle and pacifier accessories are not clearly visible in all viewing orientations of the product, as shown in the SGS test reports, ESi exemplar product photographs, and internet retailer photographs. Also, the package labeling does not identify the existence of the tiny pacifier and bottle accessories within the package. Prior to Richaline Dedios purchasing the subject Calico Critters Yellow Labrador Twins and accessories product at Walmart, the previous Calico Critters package design contained clear cellophane on the top and the pacifier and bottle accessories were positioned lower in the package such that the bottle and pacifier accessories were clearly visible from multiple perspectives.

F.



G. Prior to Richaline Dedios purchasing the subject Calico Critters Yellow Labrador Twins and accessories product, the defendants failed to properly perform a risk assessment and apply the hazard control hierarchy (safety hierarchy) to achieve an acceptable level of risk associated with the product by eliminating the small parts choking hazard. EEP corporate representative Ms. Masterson testified that she does not know what is a hazard analysis/risk assessment and she does not know if EEP has ever performed a hazard analysis or risk assessment on the Calico Critters toy line. The Calico Critters Yellow Labrador Family and other Calico Critters Twins products are packaged and sold without accessories. Indeed, after Dakotah Dedios's incident and death, the Calico Critters Yellow Labrador Twins product tiny pacifier and bottle accessories were substituted by a toy car accessory that does not entirely fit within the small parts cylinder. Prior to 2018, the Sylvanian Families Golden Labrador Baby was sold with a crib accessory, instead of a tiny pacifier accessory, where it appears that the crib accessory does not fit entirely in the small parts cylinder. Had the subject Calico Critters Yellow Labrador Twins product been sold without the pacifier and bottle accessories or had these accessories been substituted with accessories that do not fit entirely in the small parts cylinder (such as the crib and car accessories), these safer alternative designs most likely would have prevented Dakotah Dedios's fatal incident. Prior to 2018, accessory sets containing pacifiers and bottles for Calico Critters/Sylvanian Families products were sold separately from the flocked animal figures.

H. The warnings on the subject Calico Critters Yellow Labrador Twins and accessories product package do not adequately alert the purchaser that there are tiny pacifier and bottle accessories that pose a small parts choking hazard, especially given that the subject package obscures viewing these accessories as shown in the SGS test reports, ESi exemplar product photographs, and internet retailer photographs. Indeed, the Walmart.com website does not even show the pacifier accessory in its image of the product contents. The subject package references boy Twin Marley taking out his trumpet and pretending to play a song with his sister, but there is no mention of tiny pacifier and bottle accessories included within the product package. The principal display panel of the subject product only identifies the Calico Critters Yellow Labrador Twins, not the pacifier and bottle accessories. The subject product package labeling is confusing and misleading. Had the package explicitly stated that the subject product contained tiny pacifier and bottle accessories that go in the mouth, combined with

making the package such that these tiny accessories were clearly visible from multiple perspectives, the purchaser would not have been so uninformed about this safety information and would have been given proper notice about these specific small parts choking hazards in order to make a fully educated decision regarding purchasing and management of the product.

- I. There were several other technologically, economically, and functionally feasible safer alternative designs which eliminate the subject small parts choking hazard associated with the subject Calico Critters Yellow Labrador Twins and pacifier and bottle accessories, such as eliminating or substituting the small parts choking hazards so that they do not fit entirely within the small parts cylinder. These safer alternative designs most likely would have prevented Dakotah Dedios's incident and death without substantially impairing the product's utility, and were economically and technologically feasible at the time the product left the control of the manufacturer and supplier by the application of existing or reasonably achievable scientific knowledge. Indeed, following Dakotah Dedios's fatal incident, the manufacturer has already conceded that the pacifier and bottle small part accessories for the Calico Critters Yellow Labrador Twins product are not necessary and were substituted with a different toy car accessory that does not fit entirely with the small parts cylinder. Years prior to the sale of the subject product in 2018, the Sylvanian Families Golden Labrador Baby was sold with a crib accessory, instead of a pacifier accessory, where it appears that the crib accessory does not fit entirely in the small parts cylinder.
- J. At the time of sale of the subject Calico Critters Yellow Labrador Twins and accessories product, the product was defectively designed and unreasonably dangerous and posed an unreasonable risk of harm.
- K. At the time of sale of the subject Calico Critters Yellow Labrador Twins and accessories product, the defendants were negligent because they manufactured, supplied, and sold a defective and unreasonably dangerous product that did not meet applicable toy safety regulations, standards, and guidelines and created an unreasonable risk of harm due to a small parts choking hazard for an intended vulnerable child user under the age of 3. There have been seven product recalls associated with small parts choking announced by the U.S. CPSC in cooperation with International Playthings from 2003 through 2012, in addition to the 4/13/13 incident in Farmington, Utah where 22 month old James Rencher very nearly choked to death when a tiny Calico Critters plastic toy pacifier (similar to the subject pacifier accessory) lodged in his windpipe. Based upon these and the totality of the evidence presented in this report, the defendants did not take adequate steps to act in the manner of a reasonable manufacturer, supplier, and retailer of a toy [REDACTED]

[REDACTED] The deposition testimony of Ms. Masterson, which is binding on the company as the EEP corporate representative, indicates EEP's complete lack of safety awareness associated with the subject toy design, packaging, marketing, promoting, advertising, applicable safety regulations and

standards requirements, toy industry research, U.S. CPSC requirements, small parts cylinder test, market surveillance, and the like. Ms. Masterson did not even know before her deposition that if a product fits inside the small parts cylinder, then that meets the definition of a small part under the CPSC.



- M. The defective and unreasonably dangerous condition of the subject Calico Critters Yellow Labrador Twins and accessories product as designed, manufactured, supplied, and sold by the defendants proximately caused Dakotah Dedios’s incident and death.
- N. The negligent conduct of the defendants in designing, manufacturing, supplying, and selling the subject Calico Critters Yellow Labrador Twins and accessories product in a defective and unreasonably dangerous condition proximately caused Dakotah Dedios’s incident and death.
- O. There is no evidence that the defendants conducted proper market surveillance for relevant incidents. EEP corporate representative Ms. Masterson testified that she does not know what is meant by postproduction and/or post sales surveillance. According to U.S. CPSC official agency guidance on best practices ([www.cpsc.gov](http://www.cpsc.gov)), ISO 10377:2013, ISO 10393:2013, and ISO/IEC Guide 50-2014, the defendants have a responsibility to conduct market surveillance. Had they done so, they would have identified the “close call” incident in 2013 involving 22 month old James Rencher with the near-fatal similar scenario involving the same Calico Critters small parts pacifier accessory in the mouth in a child under 3 years old. ESi was able to identify this prior incident during its market surveillance research by simply performing a Google search using the keywords “Calico Critters choking incidents,” as shown in Figure 26. According to the Federal Register, “close calls” are important indicators that a risk of injury from small parts exist. Given that the defendants took action and made design changes to the subject product accessories following Dakotah Dedios’s fatal incident, it follows that they should have implemented the same design changes had they identified this previous incident information at that time. Had the defendants done so and eliminated the small parts choking hazard pacifier accessory at that time, Dakotah Dedios’s fatal incident most likely would not have occurred. In fact, Sylvanian Families Golden Labrador flocked animal baby figures were sold with a crib accessory that appears to not fit entirely in the small parts cylinder, instead of a tiny pacifier accessory that does fit entirely in the small parts cylinder, years before the subject product was sold.

All the foregoing opinions and conclusions are made within a reasonable degree of engineering certainty based upon the author's education, background, experience, review of listed documents, and inspection of exemplar Calico Critters Yellow Labrador Twins and accessories products. I reserve the right to supplement [REDACTED] in the event further relevant information becomes available.

Currently Engineering Systems Inc. charges \$350.00 per hour for my professional time. [REDACTED]  
[REDACTED]