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A Systems Approach to "Adequacy": Human Factors Analysis in Infant Formula and Nutrition Product Litigation

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Human factors experts play a critical role in infant formula and nutrition-product litigation because the central questions in these cases—what caregivers perceive, understand, retain, and ultimately do—are questions about human capabilities and limitations, not merely regulatory compliance. In the ongoing infant formula disputes, including the NEC multidistrict litigation and parallel state-court proceedings, claims often hinge on whether manufacturers provided warnings and instructions that were sufficiently clear, prominent, and actionable for caregivers and clinicians who may be operating under time pressure, fatigue, and varying levels of health literacy.

An evidence-based human factors analysis can help courts distinguish preventable, use-related risk from the inherent residual risk associated with the product. This framework clarifies what hazards were reasonably foreseeable, what aspects of communication could have been controlled through better design, and where the appropriate boundaries of responsibility fall among manufacturers, healthcare providers, and caregivers. Such expert analysis provides essential context for evaluating the adequacy of warnings and the reasonableness of manufacturer conduct under the applicable legal standards.

A human factors analysis in product-related litigation typically begins with a systematic review of the communication system at issue. This includes an examination of the design and content of labels, instructions for use, preparation charts, pictograms, and any supplemental print or digital materials, evaluated against established research on how individuals perceive and respond to warnings. A human factors expert assesses the adequacy of typography, contrast, signal words, pictograms, sequencing of steps, and the articulation of consequence and avoidance statements. This allows the expert to opine on whether the information provided was sufficiently conspicuous, comprehensible, and practical, and whether it could reasonably have supported safe behavior when read and followed.

Because directions for use must share limited labeling real estate with nutrition facts, preparation charts, and mandatory regulatory text, manufacturers frequently confront inherent constraints. A human factors expert can assist the trier of fact by explaining these constraints and how a manufacturer balanced completeness with the need for clarity and brevity. By relying on risk-communication strategies supported by peer-reviewed literature, a human factors expert can further demonstrate the reasonableness of a manufacturer's approach to informing consumers, caregivers, and healthcare professionals. Such analysis provides critical context for evaluating whether a communication system met industry expectations and foreseeable-use standards under the applicable legal framework.

Recognized frameworks can provide benchmarks. The Infant Formula Act and FDA's infant formula labeling regulations at 21 C.F.R. §107 set specific expectations for directions for preparation and use. FDA labeling requirements include directions for storage, agitation, dilution or reconstitution, sterilization of water and bottle components when necessary, pictograms depicting the major steps for preparation, a warning about the need to follow directions, and a statement about consulting a health care provider for guidance. Human factors experts can map label elements to FDA requirements, demonstrating regulatory alignment of the label, and help courts determine whether alleged inadequacies reflect a true warning defect or a broader, multi-actor systems issue.

In litigation involving microbial hazards, whether the on-package and caregiver-facing materials reasonably conveyed risk associated with the product, environmental factors (e.g., water source), and user behavior (e.g., refrigeration, disposal, cleaning) may be questioned. Public health guidance from the CDC and the FDA emphasizes hand hygiene, equipment sanitation, safe preparation, and, when appropriate, the use of ready-to-feed sterile liquid formulas for higher-risk infants. In such litigation, human factors experts can identify the expected and proper channels to provide additional information, examine whether on-package instructions and caregiver-facing instructions obtained from various sources reasonably conveyed such information, whether caregivers carried out the steps provided or asked for, and whether the lack of such information on the package affected the behavior of caregivers and contributed to foreseeable misuse.

What caregivers can reasonably accomplish must be understood against documented literacy constraints. Research has found that a large proportion of U.S. caregivers have limited health literacy (Yin et al., 2009).

A study evaluating powdered formula instructions found readability and comprehension difficulty for critical sections on a label (Wallace et al., 2016). A human factors expert can separate what was knowable in the relevant time periods, what constraints exist on label real estate, and whether additional information would reasonably improve comprehension, oversimplify technical requirements, or become a source of information overload for caregivers.

Because many infant formula and pediatric nutrition products are administered under clinician direction, particularly in NICU environments, a human factors analysis can help clarify the appropriate division of responsibility for risk communication. This includes distinguishing between information intended solely for healthcare professionals and the messages that must appear on consumer-facing labeling. In practice, it is reasonable for caregiver-directed materials to focus on tasks within the caregiver's control, such as hygiene practices, mixing procedures, storage conditions, and discard intervals. Conversely, information directed at clinicians should support clinical judgment, product selection, and individualized patient care.

Publicly available resources, such as CDC guidance on bottle-feeding and equipment cleaning, along with materials from state nutrition programs, illustrate the type of step-wise, concrete behavioral instructions that can meaningfully reduce risk when aligned with on-package directions. Harmonizing these evidence-based practices with product labeling can improve compliance, mitigate microbial hazards, and help prevent dosing and preparation errors. A human factors framework provides the structure needed to evaluate whether the communication system reasonably supported each user group in carrying out their respective responsibilities.

None of this shifts all responsibility to either manufacturers, health care providers, or caregivers; rather, it reframes "adequacy" around reasonableness and systems thinking. Even adequate warnings and instructions cannot eliminate risk when hazards are inherent and tasks are complex; but they can measurably reduce use-related errors, if read and followed. In highly contested matters, a focused human factors analysis can be particularly helpful by answering questions such as:

- Given the state of knowledge and standards at the time, did the communication system make it reasonably likely that intended users would be able to notice, understand, and follow the steps that could reduce risk?
- Should risks about, for example, Enterobacter, Cronobacter or NEC be reasonably expected to be on consumer-facing labels versus conveyed within clinician-directed feeding protocols?
- Should products handed out by hospitals be expected to be accompanied by instructions from health care providers?
- Did marketing content undermine warnings?
- Did the company do enough to keep pace with external guidance and emerging knowledge?

Extensive research in warnings science demonstrates that even well-crafted warnings may fail to elicit safe behavior if they are not noticed, read, understood, and followed. In the courtroom, systematic human factors testimony can clarify that warnings alone cannot eliminate all risk, nor can they replace the behavioral safeguards, environmental controls, and professional clinical judgment required in hospital and home settings, particularly when caring for medically fragile infants. Human factors experts can, however, evaluate whether a manufacturer took reasonable, evidence-based steps to reduce use-related risk. This includes assessing whether on-package communications were consistent with prevailing standards and public health guidance at the time, and whether the manufacturer maintained an appropriate process to monitor real-world use, incorporate feedback, and improve its communication system over time. Such analysis helps delineate the respective responsibilities of manufacturers, healthcare providers, and caregivers, providing the court with a clear framework for understanding how risk is distributed and managed across users and contexts.

HOW CAN SECRETARIAT ASSIST?

Secretariat's Human Factors experts assist courts and litigants in infant formula and nutrition-product litigation by evaluating whether warnings and instructions reasonably supported safe use under foreseeable conditions. We assess whether caregiver- and clinician-facing communications could be noticed, understood, and followed in real world contexts. Our analyses examine the full communication system against applicable FDA requirements, prevailing public health guidance, and human factors science available at the relevant time and differentiates alleged warning or instruction defects from risks reasonably addressed through clinical judgment, hospital feeding protocols, and caregiver practices. This systems-based analysis provides technical context to assess the reasonableness of manufacturer conduct and understand the role relevant stakeholders play in managing risk.

REFERENCES

1. Yin, HS, Johnson, M, Mendelsohn, AL, Abrams, MA, Sanders, LM, & Dreyer, BP (2009). The Health Literacy of Parents in the United States: A Nationally Representative Study. Pediatrics, 124(Suppl 3), S289–S298.

2. Wallace, LS, Rosenstein, PF, and Gal, N (2016). Readability and Content Characteristics of Powdered Infant Formula Instructions in the United States. Maternal and Child Health Journal, 20, 889-894.

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