

## *Methodology*

A deliberately overinclusive data set of cases was assembled through multiple searches of the Westlaw and LEXIS databases. The searches covered decisions in state and federal courts, including published and unpublished decisions, using all combinations of two sets of search terms. The first set sought to identify all decisions in which a court addressed comment k, whether by name or by reference, and used the terms “comment k,” “cmt. k,” “unavoidably unsafe,” and “unavoidabl!”. The second set sought to identify all decisions in which a court addressed medical devices, and used the terms “device” and “medical device.” To limit the results to decisions addressing the application of comment k to medical devices, the Boolean connector “AND” was used; queries were thus “comment k” AND “device,” “unavoidably unsafe” AND “medical device,” and all remaining permutations. The Westlaw search engine was also queried using the West Key Number system codes 313Ak113 (Strict Liability) and 313Ak223 (Health Care and Medical Products), with results filtered for cases containing the terms “comment k,” “cmt. k,” or “unvoidabl!”.

The identified cases were first screened for duplicates, which were removed. A total of 402 unique decisions were identified. Each of these decisions was read by the author to identify cases that did not involve an allegedly defective medical device or did not discuss comment k to section 402A of the *Restatement (Second) of Torts* for exclusion. Based on the initial screening, 196 cases were excluded, comprising cases involving litigation over other products such as drugs, vaccines, tobacco, and asbestos (n=114) or an absence of an analysis of comment k (n=61). Other cases were excluded because they were addressed by subsequent cases (n=11), were only case filings (n=6), or were duplicates with different reporter (Westlaw, LEXIS) designations (n=4).

This process resulted in a data set containing 206 judicial decisions, which were issued between April 27, 1978, and June 26, 2024. Data from each case was then coded. Some information, such as the court in which the case was decided and the date of the

decision, was downloaded from the Westlaw and LEXIS search engines directly into the database. Other information, such as the procedural posture of the decision, was clearly stated in most cases.

The data needed to address questions concerning how courts applied comment k were collected through the use of well-established quantitative, systematic content-analytic methodologies.<sup>374</sup> For this, a coding form and a coding manual were developed in incremental fashion based on the language of comment k, the analysis presented in Part II of this paper, and an initial reading of a subset of the device cases. An overarching goal was to minimize the impact of subjectivity, and thus to maximize the reproducibility of the findings. To the greatest extent possible, subjectivity was limited by carefully framing the data to be coded into yes or no questions. The data points collected are listed in Part C and the coding book instructions are presented in Part D. Of note, many of the data points were not relevant to the present Article, but will be used in future works.

Using the finalized coding form and manual, data points were coded by the author for each case. Additionally, eighty-three (40 percent) of the cases were also independently coded by two additional readers (two law student research assistants), in order to assess interobserver variability in coding. All of the cases were also coded a second time by the author for an assessment of intra-observer variability.

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374. For a background on examples of the methodologies used in quantitative content analysis in legal scholarship, see generally Hall & Wright, *supra* note 257, at 65-66 (cataloging the use of the technique and attempting to establish a set of best practices); William Baude, Adam S. Chilton & Anup Malani, *Making Doctrinal Work More Rigorous: Lessons from Systematic Reviews*, 84 U. CHI. L. REV. 37, 37 (2017) (describing and applying a four-step process “that could be used whenever someone is trying to make objective claims about the state of legal doctrine” (emphasis omitted)); Samuel Issacharoff & Florencia Marotta-Wurgler, *The Hollowed-Out Common Law*, 67 UCLA L. REV. 600, 608-09, 628-30 (2020) (employing quantitative content analysis to derive a model of how and where state common law in cases involving clickwrap, shrinkwrap, and browserwrap contracts); Oren Bar-Gill, Omri Ben-Shahar & Florencia Marotta-Wurgler, *Searching for the Common Law: The Quantitative Approach of the Restatement of Consumer Contracts*, 84 U. CHI. L. REV. 7, 8 (2017) (employing quantitative content analysis in their role as Reporters for a new Restatement of Contracts “to answer the question of what rules the majority of courts and jurisdictions follow”); William M. Landes, Lawrence Lessig & Michael E. Solimine, *Judicial Influence: A Citation Analysis of Federal Courts of Appeals Judges*, 27 J. LEGAL STUD. 271, 271 (1998) (using quantitative analysis of judicial decisions to study the influence of individual judges).

Statistical analyses were performed using Minitab Statistical Software version 21.1.0.0.