



CRA Insights: Life Sciences

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Economic analysis of class certification issues

Class actions often generate controversy, frequently related to the concern that the outcome of the class certification decision can lead to settlements that may not maximize social welfare. A hesitancy to consider substantive economic analysis during the class certification stage of litigation contributes to this concern, but forays into more advanced economic consideration have become more common and now look to be the new standard following the United States Court of Appeals for the Third Circuit's opinion in *In re Hydrogen Peroxide Litigation* (MDL 1682). In its ruling, the Third Circuit held, among other issues, that district courts must:

- Resolve factual and legal disputes relating to class certification even if they overlap with merits consideration, and
- Consider expert testimony in resolving such disputes.

The Life Sciences Practice at Charles River Associates has successfully introduced substantive economic analysis during class certification, often involving challenges to the commonality requirement of Rule 23 for classes of direct or indirect purchasers. Three types of analysis from CRA engagements provide examples.

Changes in business practices

Do the similarities among class members persist when considering a counter-factual world lacking the cause of action? CRA investigated the business practices of purported direct and indirect class members for litigation in which a drug manufacturer was accused of having acted anticompetitively to delay generic entry. If competitive forces in the counter-factual world lead to significant deviations in business practices by certain class members, then inclusion in a class where others act consistently is likely to generate conflict. Examples include:

- **Alternative distribution channels:** Branded and generic drugs are distributed through different channels. Building a class representing disparate channels risks inconsistency in actions alleging delays in the availability of generic options.
- **Type of therapy:** Some therapies or devices have close substitutes, so that the issues in litigation might affect their sales as well. In such a case, the proposed class might create inconsistency based on which members would have opted for close substitutes rather than different forms of therapy and the cost and efficacy implications of that choice.
- **Site of care:** Some therapies or devices represent the only form of treatment available at a site of care, so that a counter-factual world that eliminates a therapeutic option might result in patients seeking different sites of care (e.g., hospital rather than outpatient clinic), with disparate patient volume and revenue consequences for potential class members.

Economic analysis capable of demonstrating the dynamic competitive pressures faced by potential class members in actual and counter-factual circumstances can provide clear examples that violate the commonality requirements of a class, especially if supplemented with industry expertise demonstrating the factors that support such disparate commercial behavior.

Class segmentation

Do individual differences predominate such that potential class members could only be grouped into smaller categories than proposed by plaintiffs? Are there segments of the proposed class membership which should be excluded from consideration? As an example, CRA analyzed the patient flow for members of a class alleging economic fraud related to product liability claims. Segmentation techniques and a patient flow diagram demonstrated the winnowing of the proposed class through sequential consideration of the efficacy, concurrent use, and costs of alternative therapeutic options.

The implications for patients were significant—many patients paid less in the presence of the therapy at issue than they would have otherwise. Similarly, third-party payers, who provided insurance for the patients, faced similar segmentation—significant percentages of covered lives that would have realized higher costs in the absence of the therapy. Further, as some therapeutic options would have included a shift in the site of care, some health care providers that used the therapy at issue would not have seen the patients otherwise. Thus, some health care providers benefited from the availability of the therapy and clearly would not have common interests with those who would have benefited from using alternative therapies.

Inconsistency in damages outcomes

Why evaluate the proposed damages methodology when courts often have minimal expectations for damages while addressing class certification? The damages techniques required during class certification can be used to demonstrate commonality or the lack thereof. When analyzing the pricing behavior of a healthcare provider, CRA demonstrated two ways in which the damages methodology demonstrated a lack of commonality. First, by pairing the plaintiffs' damages methodology with another that was similar and as reasonable, *a priori*, CRA identified wide variances in outcomes that belied coordinated interests among proposed class members. This simple approach noted that if the same group were to have significantly different outcomes based on two similar and reasonable damages approaches, then the class would be overbroad and include too many disparate interests.

A second approach, using a single reasonable damages methodology, demonstrated that small deviations in counter-factual circumstances created conflict among the proposed class members. As demonstrated by this approach, if the common interests of the group were so tenuous that small changes in basic issues of relevance (e.g., reimbursement policies, purchasing requirements) drove large variations in damages, then this volatility demonstrated the need to winnow the proposed class to produce more consistent outcomes. Importantly, it was not the damages model *per se* that was the basis for the challenge to commonality in either approach, but the variations in outcomes that were the direct result of economic analysis.

Conclusions

Recent changes in the standards for economic evaluation of class certification provide an opportunity to address substantive case issues before merits evaluation. The case studies discussed above provide the following implications for pursuing class certification after *Hydrogen Peroxide*:

- There is now the possibility of, and perhaps the requirement for, substantive economic evaluation during class certification consideration.
- Addressing substantive issues earlier in the litigation will highlight the need for earlier discovery to support economic arguments, with efficiency gains accruing to those who can more readily focus on relevant issues.

- Industry experience is very useful in the context of class certification analysis, as it provides context for the evaluation of business models of potential class members and identifies issues of relevance and avenues for efficient discovery.

About CRA's Life Sciences Practice

We provide life sciences companies, law firms, and regulatory agencies across the globe with the industry experience and analytical expertise needed to address the industry's toughest issues. We have developed a reputation for rigorous and innovative analysis, careful attention to detail, and the ability to work effectively as part of a wider team of advisers.

CRA has offices throughout the world, including European offices in London, Brussels, and Frankfurt; United States offices in Boston, Chicago, New York, Oakland, and Washington DC; and other international offices in Toronto, Bahrain, and Hong Kong.

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