

Introduction

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Greetings again, readers! Any comment about the continuing COVID-19 pandemic and its impact on this volume would be trite by now. Suffice it to say, the original plan was to return to a paper publication to be distributed at the 2022 FDLI Annual Conference, but with the decision to make the conference only semi-in-person, it made sense to revert to an ebook again for our 2021–2022 edition of Top Food and Drug cases.

What this edition lacks in tree by-products, it makes up for in quality of content. This year we have fourteen chapters on top cases or clusters of cases, more than we have had for the past few years, perhaps reflecting something of a return to business as usual in both litigation and regulatory enforcement. As always, we span all aspects of the food, drug, and medical device sectors, and even cover developments outside the food and drug realm where our authors decided that they have important implications for the food and drug community. All of our contributors hope that FDLI’s members continue to find our volume informative, interesting, and worth archiving for future reference. As always, we deliver a heads-up on Cases to Watch at the end of the book, to alert you to potential developments in the latter half of 2022 and beyond.

Several of our cases always cover developments at FDA. This year, Sara Koblitz covers the *Catalyst v. FDA* case, an important development in Orphan Drug Act approval. The team of Véronique Li, Faraz Siddiqui, and Jeff Gibbs tells us about a key case regarding FDA’s ban on shock treatment devices for mental conditions. Naomi Igra writes about an important circuit court decision regarding FDA’s stem cell procedure approval process. Jackie Chan and Dan Logan have written up an important case about FDA’s Generally Recognized as Safe (GRAS) rules.

Two of our cases this year relate to another key agency, the Federal Trade Commission (FTC), and the implications of recent developments there for the food and drug sectors. Bryant Godfrey and Tina Papagiannopoulos discuss developments in the wild, high-profile tale of “pharma bro” Martin Shkreli, with its consequences for competition and other enforcement in the prescription drug sector. Lynn Tyler covers a key FTC matter involving FTC’s authority to seek monetary recovery as a consumer protection remedy that, while not a food or drug case, has broad implications for any industry sector in which FTC is active. In addition, Jonathan Havens discusses the overall state of regulation of cannabis products.

Our other chapters address private litigation. Ginger Pigott and Michael Goodman cover an important development in the learned intermediary doctrine in failure-to-warn product liability cases. Mital Patel and Francisco Cabrera Lopez discuss a key appellate decision and its implications for the adequacy of pleading in the current

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significant wave of false labeling cases involving food products. I weigh in on an important constitutional challenge to the tide of litigation in California to enforce the state’s mandated Proposition 65 warnings as they apply to acrylamide in foods. Bill Janssen reviews a key case relating to the pleading standard in product liability cases. James Beck summarizes an important Oklahoma Supreme Court decision, and related developments, on the ability of state Attorneys General to apply public nuisance and other laws to hold pharmaceutical companies liable for America’s opioid abuse epidemic. Genna Liu, Rene Befurt, and Rebecca Kirk Fair discuss another important food labeling precedent relating to the interpretation of labels by courts in false advertising cases. Finally, from outside the food and drug area, Anand Agneshwar, Anna Thompson, and Jocelyn Wiesner reports on the implications of a major case on personal jurisdiction over out-of-state defendants.

As usual, we include two composite chapters summarizing types of developments that don’t necessarily generate “cases” or court decisions. Lauren Farruggia again describes important regulatory and enforcement developments from the past year, and Justine Lenehan covers significant settlements between federal enforcement agencies and their targets over the course of 2021. For our final chapter, several authors nominated in-progress cases that we think are worth watching for the balance of 2022. As always, there is more than a little to interest any active practitioner in the food, drug, and related spaces in these pages.

I and FDLI sincerely appreciate the contributions of all of our authors, many of whom have been faithful contributors for several years. We hope this summary of important 2021 and early 2022 matters in the food and drug area provides you with the same education and enjoyment as our previous volumes. On behalf of the entire Top Cases team, we wish our audience a happy, healthy, and safe year.