

Among the recent decisional law excerpted in the new edition, you will find the following:

- Chap. 3(B) (medical devices):
 - *Ivy Sports Med. v. Burwell* (D.C.Cir.2014) (invalidating withdrawal of PMN for ReGen’s Collagen Scaffold).
- Chap. 4(A)(1) (Rx vs. OTC):
 - *Tummino v. Torti* (E.D.N.Y.2013) (invalidating age restriction on OTC switch of Plan B).
- Chap. 4(B)(1) (advertising to professionals):
 - *Christopher v. SKB* (U.S.2012) (holding that sales reps are not entitled to overtime pay); *ONY, Inc. v. Cornerstone Therapeutics* (2d Cir.2013) (rejecting a Lanham Act claim premised on the publication of an allegedly misleading comparative efficacy study).
- Chap. 7(A)(1) (knowability and the duty to warn):
 - *Mack v. Stryker* (8th Cir.2014) (risk of chondrolysis from pain pump was unknowable).
- Chap. 9(A)(2) (private payers):
 - *Burwell v. Hobby Lobby* (U.S.2014) (RFRA entitled the owners of closely held corps. with religious objections to opt out of ACA mandated coverage for contraceptives).
- Chap. 9(A)(3) (experimental exclusion):
 - *Boldon v. Humana Ins.* (D.Ariz.2006); *Jacobs v. Guardian Life Ins.* (N.D.Ill.2010).
- Chap. 9(C)(2) (state efforts at price controls):
 - *Ouellette v. Mills* (D.Me.2015) (state law allowing importation impliedly preempted).
- Chap. 10(A)(1) (patentable subject matter):
 - *Mayo Collaborative Servs. v. Prometheus Labs.* (U.S.2012) (diagnostic processes were unpatentable laws of nature); *Ass’n Molecular Pathology v. Myriad Genetics* (U.S.2013) (invalidating most gene patents).
- Chap. 10(C) (antitrust):
 - *FTC v. Actavis* (U.S.2013) (applying the rule-of-reason standard to reverse payment settlements); *N.Y. ex rel. Scheiderman v. Actavis* (2d Cir.2015) (affirming an injunction against manufacturer of Namenda for anticompetitive “product hopping”).

- Chap. 11(B)(1) (biologics):
 - *U.S. v. Regenerative Scis.* (D.C.Cir.2014) (sustaining the FDA assertion of jurisdiction over a clinic's autologous stem cell procedure).

- Other significant new decisions discussed in the notes include *Whole Woman's Health v. Hellerstedt* (U.S.2016) (Texas statute unduly burdened access to abortion), and *Mutual Pharm. Co. v. Bartlett*, 133 S.Ct. 2466 (2013) (implied preemption of design defect claims).

- Important legislative developments (discussed where relevant in various notes) include the FDA Safety and Innovation Act (2012) and the Drug Quality and Security Act (2013). New regulatory developments (and/or brief case studies) include laboratory-developed tests (LDTs), mobile devices and medical apps, and final rules on electronic cigarettes (noted in Chap. 1(B)(3)); a crackdown on pharmacy compounding after a nationwide outbreak of fungal meningitis (noted in Chap. 1(C)); responses to opioid abuse and greater attention to patients' behavioral responses (noted in Chap. 1(E)); the proliferation of state "right to try" laws (noted in Chap. 2(D)); use of "paper" NDAs (noted in Chap. 3(A)(2)); restrictions on tanning beds (noted in Chap. 3(B)); the prospect of "unswitching" OTC drugs (noted in Chap. 4(A)(1)); discontinuation of the pregnancy categories in Rx drug labeling, and problems with power morcellators (noted in Chap. 4(A)(2)); disclosure of gifts to physicians in CMS's open payments database (noted in Chap. 4(B)(1)); responses to promotional use of social media (noted in Chap. 4(B)(2)); bisphosphonate drugs and litigation over failures to disclose the risk of osteonecrosis of the jaw (noted in Chap. 7(A)(1)); malpractice issues posed by use of the da Vinci surgical robot (noted in Chap. 8(B)(2)); growing complaints about price gouging (noted in Chap. 9(C)(3)); continued drug shortages (noted in Chap. 9(D)); experience with the priority review voucher program to incentivize the development of treatments for neglected tropical diseases and rare pediatric cancers (noted in Chap. 10(B)(2)); PTO's *inter partes* review (noted in Chap. 10(B)(3)); the advent of biosimilars (noted in Chap. 11(A)); relaxation of the prohibition on blood donations by gay men (noted in Chap. 11(B)); lab-grown organs and fecal microbiota transplants (noted in Chap. 11(B)(1)); gene editing with CRISPR-Cas9 (noted in Chap. 11(C)(2)); and tricky bioethical questions posed by fully implanted heart-assist devices (noted in Chap. 11(D)(1)).