

1. Record Nr.	UNINA9910633932303321
Titolo	Cancer drug safety and public health policy : a changing landscape // Charles Bennett, Courtney Lubaczewski, Bartlett Witherspoon, editors
Pubbl/distr/stampa	Cham, Switzerland : , : Springer, , [2022] ©2022
ISBN	3-031-04402-9
Descrizione fisica	1 online resource (171 pages)
Collana	Cancer treatment and research ; ; Volume 184
Disciplina	616.99406
Soggetti	Cancer - Treatment Medical policy Oncology Antineoplastic Agents - standards Neoplasms - drug therapy
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Nota di bibliografia	Includes bibliographical references and index.
Nota di contenuto	Intro -- Preface -- Contents -- Editors and Contributors -- 1 Fluoroquinolone-Associated Disability and Other Fluoroquinolone-Associated Serious Adverse Events: Unexpected Toxicities Have Emerged in Recent Years -- 1.1 Introduction -- 1.1.1 FQ Adverse Event Drug Label Warnings -- 1.1.2 FQ Drug Label Changes (See Table 1.1 for Levofloxacin Label Changes) -- 1.1.3 FDA Reports of FQ Adverse Events -- 1.1.4 November 5, 2015, FDA Advisory Committee Meeting Identifies FQAD -- 1.1.5 November 5, 2015, FDA Advisory Committee Votes -- 1.1.6 Boxwell FDA FQ Data Compared with Social Media FQ Reports -- 1.1.7 Gender -- 1.1.8 Specific FQs -- 1.1.9 Duration of FQAD -- 1.1.10 FQAD: Reasons for Which FQ was Prescribed -- 1.1.11 FQAD Specific Events -- 1.1.12 Possible Mechanism of FQ Toxicities -- 1.1.13 Another Possible Pathophysiologic Mechanism: Matrix Metalloproteinase Toxicity -- 1.1.14 FQ-Associated Peripheral Neuropathy -- 1.1.15 Levaquin Clinical Trials Completed Prior to FDA Approval in 1997 -- 1.1.16 2001 FDA FQ Review -- 1.1.17 2003 FDA FQ Review -- 1.1.18 2008 FDA Pediatric Levofloxacin Review -- 1.1.19 2010 Pfizer Report -- 1.1.20 2011 Levaquin Postmarketing Review --

1.1.21 2013 FDA Review -- 1.1.22 2014-Present Media Reports
Regarding FQs -- 1.1.23 2014 FDA Advisory Committee Comments --
1.1.24 2014 FDA Dear Healthcare Professional Letters -- 1.1.25 2014
Citizen Petition -- 1.1.26 2014 Meeting with U.S. Senate Health
Committee -- 1.1.27 2015 Meeting with FDA -- 1.1.28 2015 FQ Case
Studies -- 1.1.29 2015 FDA Advisory Committee Meeting -- 1.1.30
2015 FDA Listening Session -- 1.1.31 2016 FQ Neuropsychiatric Study
-- 1.1.32 2016 FQ Label Updates -- 1.1.33 2016 FDA Response to
Citizen Petition -- 1.1.34 2018 FQ Nature Article -- 1.1.35 2019
Citizen Petition -- 1.1.36 2019 FQ Neuropsychiatric Toxicity Study --
1.2 Discussion -- 1.3 Conclusions.
1.3.1 Recommendations -- 1.3.2 Significance of This FQ Study -- 1.4
REMS Request -- References -- 2 Biosimilar Epoetin in the United
States: A View from the Southern Network on Adverse Reactions -- 2.1
Introduction -- 2.1.1 Regulatory Approval for Epoetin Biosimilar in the
United States -- 2.1.2 Chemistry, Manufacturing, and Controls -- 2.1.3
Biological Activity -- 2.1.4 Pharmacology/Toxicology -- 2.1.5
Immunogenicity -- 2.1.6 Clinical Pharmacology -- 2.1.7 Clinical
Efficacy and Safety -- 2.1.8 Risk Evaluation and Mitigations Strategy
(REMS) -- 2.1.9 Extrapolation -- 2.1.10 Findings of the Oncology Drug
Advisory Committee (ODAC) of the FDA -- 2.1.11 Patents and Litigation
-- 2.1.12 Naming and Labeling -- 2.1.13 Interchangeability -- 2.1.14
Substitution -- 2.1.15 Pharmacovigilance and Immunogenicity --
2.1.16 Lessons from the European Union (EU) Countries -- 2.1.17
Lessons from Japan -- 2.2 Conclusions -- References -- 3 Policing of
Drug Safety Information Dissemination Under the False Claims Act --
3.1 Introduction -- 3.1.1 The Settlement -- 3.1.2 Lessons Learned and
Legal Precedent -- 3.1.3 Future of Policing Drug Safety Efforts -- 3.2
Conclusion -- References -- 4 Translating Research into Health Policy:
The Citizen Petition Experience with the Food and Drug Administration
-- 4.1 Introduction -- 4.1.1 The Citizen Petitions -- 4.2 Conclusions
-- 4.2.1 Policy Implications -- References -- 5 Systemic Barriers and
Potential Concerns from Reporting Serious Adverse Drug Reactions --
5.1 Introduction -- 5.2 Findings of Litigation Risks -- 5.2.1 Fear of
Being Included in a Lawsuit Against the Manufacturer -- 5.2.2 Fear of
Being Sued for Libel -- 5.2.3 Fear of Personally Being Sued for
Malpractice -- 5.2.4 Fear of Physician Partners Being Sued for
Malpractice -- 5.3 Professional Retaliation.
5.3.1 Fear of Exclusion from Cooperative Industry-Sponsored Clinical
Trials -- 5.3.2 Fear of Jeopardizing Existing Academic Collaborations
-- 5.3.3 Fear of Being Excluded from a Pharmaceutical Corporation's
Speaker's Bureau -- 5.4 Regulatory Considerations -- 5.4.1 Concern
that no Response from the FDA Was Likely -- 5.4.2 Concern that no
Response from the FDA Was Needed -- 5.5 Discussion -- References
-- 6 Was There Something Rotten in Denmark: Nephrogenic System
Fibrosis Cases Occurring in Copenhagen -- 6.1 Introduction -- 6.1.1
European Actions -- 6.1.2 Actions of the Manufacturer of Gadodiamide
-- 6.2 Basic Science Considerations -- 6.3 Explanations for the Danish
Findings -- 6.4 International Considerations -- 6.5 Summary --
References -- 7 Rituximab-Associated Progressive Multifocal
Leukoencephalopathy: A Twenty-Year Update -- 7.1 Introduction --
7.2 Methods -- 7.3 Results -- 7.4 Case Series -- 7.4.1 Periodic Safety
Update Report, Global Safety Database, EudraVigilance Database, and
FAERS Database -- 7.5 Epidemiologic Studies -- 7.5.1 PML-Related
Safety Notifications from Market Authorization Holders for Rituximab in
the US and Europe -- 7.6 Discussion -- References -- 8 Maximum
Accuracy Machine Learning Statistical Analysis-A Novel Approach --
8.1 Introduction -- 8.1.1 Data Analysis in Practice -- 8.1.2 Logistic

Regression (MELR) Analysis -- 8.1.3 Using ODA to Maximize the Accuracy of the MELR Model -- 8.1.4 Novometric CTA Models Explicitly Maximizing ESS -- 8.2 Conclusion -- References -- 9 Investigating Severe Adverse Reactions: Examples of the ANTICIPATE Methodology at Work -- 9.1 Introduction -- 9.1.1 The Toxicities -- 9.1.2 HX575-Associated PRCA -- 9.1.3 Gadodiamide-Induced Nephrogenic Systemic Fibrosis -- 9.1.4 Peginesatide-Associated Anaphylaxis -- 9.2 The ANTICIPATE Evaluation -- 9.2.1 Signal Detection -- 9.3 sADR Data Analysis.

9.3.1 Root Cause Analyses/Toxicity Eradication -- 9.4 Conclusion -- References -- 10 Consequences to Patients, Clinicians, and Manufacturers When Very Serious Adverse Drug Reactions Are Identified (1997-2019): A Qualitative Analysis from the Southern Network on Adverse Reactions (SONAR) -- 10.1 Introduction -- 10.2 Methods -- 10.3 Results -- 10.4 Clinical and Economic Impact -- 10.5 Harms to Clinicians -- 10.6 Harms to Manufacturers, Actions by Regulatory Agencies, Financial Payments, and Attempts to Discredit Physicians -- 10.7 Discussion -- References -- 11 Moderna, Pfizer-BioNTech, and Johnson & Johnson/Janssen Post-Covid Vaccine Hematological Adverse Events Including Cerebral Venous Sinus Thrombosis (CVST), Thrombotic Thrombocytopenia (VITT), Blood Clots, Increased Vaginal/Menstrual Bleeding and/or Miscarriage, Stillbirth Delivery, or Premature Birth -- 11.1 Introduction -- 11.1.1 Study Implementation -- 11.2 Methods -- 11.3 Results -- 11.3.1 Blood Clot Related Events -- 11.3.2 Vaginal/Menstrual Bleeding AEs -- 11.3.3 Miscarriage, Stillbirth Delivery, or Premature Birth AEs -- 11.4 Conclusions -- 12 Investigating Novel Genetic Markers for Fluoroquinolone Associated Disorders -- 12.1 Introduction -- 12.1.1 Timeline of Events -- 12.1.2 Background of CYP2D6 -- 12.2 Conclusion -- References -- Index.
