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Nota di contenuto	Patient awarenessPractitioner attitudes; Diagnosis; Chapter 4 Gaming the system: the role of the pharmaceutical industry; Normal drug development and drug repurposing development; Gaming the system; Orphan use; Pharmaceutical marketing; Expanding uses for non-pharmaceuticals; DTC advertising; Patents and genericisation; Conclusion; Chapter 5 Do no harm: Safety and efficacy; Relative safety; Different therapeutic uses; Chronic versus acute dosing; Different dose; Differences between children and adults; Other patient populations; Fatal ADRs; Quality of evidence; Strong evidence; Poor evidence Doctors do not know evidenceProximity of off-label to on-label; Debunking medical myths; Chapter 6 Liability, injustice and reimbursement: who should pay?; A prescriber's ethical and professional duties; Medical professional participation in off-label promotion; A prescriber's legal position; Consent; Liability; Reimbursement; Compendia; NICE; Compassionate access; Cost, as a driver for off-label medicine; Chapter 7 The role of regulation in off-label medicine; Regulators do not regulate medical practice; Off-label marketing; Off-label fines; Whistle-blowers; European situation Tip of the icebergFree speech; Chapter 8 Justifying unapproved medicine; Constraints on making changes; Moves to enhance off-label medicine; Diagnosis shifting; A partial solution: clinical trial

transparency; A solution based on increased regulatory supervision; My solutions; Professional standards; Reimbursement and pricing; Outcomes; Conclusion; References; Index; Supplemental Images; End User License Agreement

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## Sommario/riassunto

Today's medicines are regulated for their efficacy and safety and, once approved, they can be marketed for certain uses as justified by the data. Regulatory bodies in developed countries are constituted by legal statute and operate as parts of government, ostensibly in the interests of the people as patients. But once approved, medicines can be used for any purpose the prescriber thinks fit and appropriate for the patient. One in five prescriptions is therefore written outside regulatory purview. Off-label Prescribing looks into the corners of our medicated lives, where drug regulation ru

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