

The Fourth International Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum

Preconference I: International Compliance Program Basics

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Baker & McKenzie, Frankfurt

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Current Climate



Settlements in the US


Case	Type of Case	Fines / Penalties
TAP	Drug Samples, Inducements	\$885 Million
Astra Zeneca	Drug Samples, Marketing Misconduct	\$355 Million
Bayer	Lick & Stick Re-labeling	\$257 Million
Bayer	Average Wholesale Price	\$14 Million
Glaxo SmithKline	Lick & Stick Re-labeling	\$88 Million
Pfizer	Medicaid Rebate Case – Undisclosed rebates	\$49 Million
Pfizer	False Claims, Violations of Food, Drug & Cosmetic Act	\$430 Million
Cephalon	Marketing Practices; False Billings to Medicaid	\$425 Million
Schering-Plough	Best Price / Anti-kickback	\$346 Million
Tenet Healthcare	Underpaid rebate allegations	\$900 Million
King Pharmaceuticals	Underpaid rebate allegations	\$124 Million
Merck Pharmaceuticals	Underpaid rebate allegations	\$649 Million
Purdue Pharma	Misbranding of Oxycontin	\$634 Million

Category of cases

- Marketing/labeling issues (including Off-Label allegation)
- Kickback payments
- Fraud and drug reimbursement claims
- Best price/rebate violations



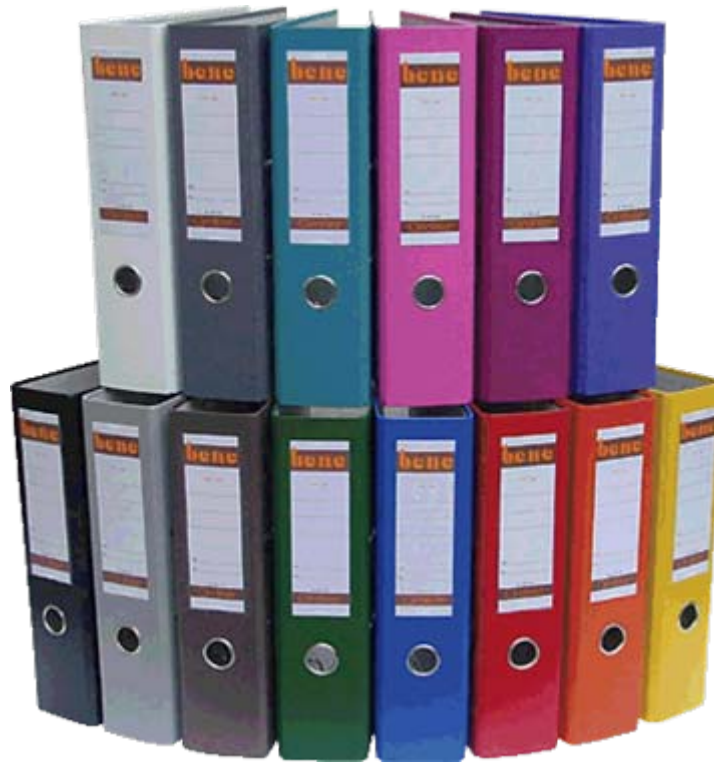
Having good intentions is
not enough anymore



“An organization shall... exercise, due diligence to prevent and detect criminal conduct; and otherwise promote an organizational culture that encourages ethical conduct and a commitment to be in compliance with the law”

USSC 2005, Federal Sentencing Guidelines

Elements of an effective compliance and ethics program




Effective compliance program

Establish standards and procedures:

- Up-to-date compliance policies
- Effective reporting and remedial procedures
- Written, complete and specific

Effective compliance program

- Clinical trial services
- Consulting agreements
- Invitations relating to conferences
- Hospitality and gifts
- Educational grants
- Charitable contributions
- Promotional materials and advertisements
- Supply of medicinal products providing of scientific information
speaker agreements
- Research agreements, lease agreements, rebate agreements



The organization shall take reasonable steps to ensure that the organization's compliance and ethics program is followed, including monitoring and auditing to detect criminal conduct.

USSC 2005, Federal Sentencing Guidelines Manual

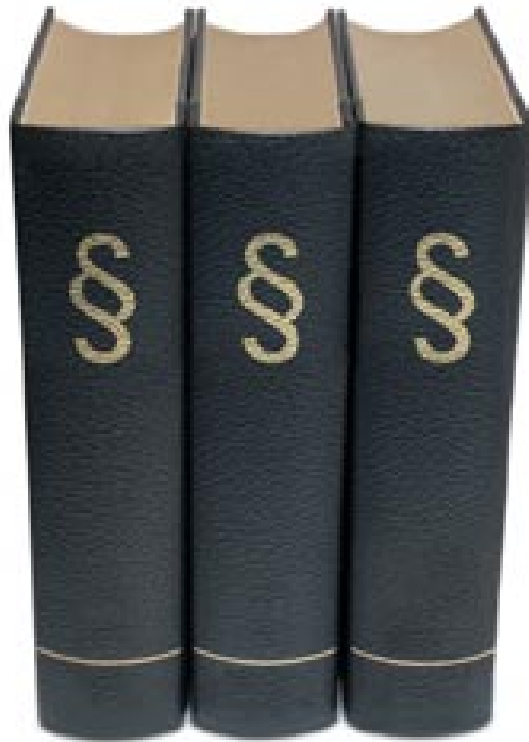
Effective training



Effective monitoring and auditing



Culture of compliance



Response and remedial action



A worldwide compliance program





Compliance in third party supplier and distribution arrangements



Compliance in an M&A transaction



Compliance tools



Consequences of compliance review

Risk of being in compliant





Conclusions

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