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The US FCPA and UK Bribery Act: How a $100 Payment Could Wreck a Multi-Million Dollar Drug or Device Clinical Trial

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Clinical Trials and Corruption Risk

- Issue: Paying a government official to conduct a sham clinical trial:
  - Favorable action with respect to the company's products in the official's role on a public hospital formulary board
  - Favorable action with respect to the company's products in connection with the official's role on government advisory panel or in connection with government insurance programs
  - Favorable action with respect to the company's products in the official's role as a publicly-paid prescribing doctor

Clinical Trials and Corruption Risk

- Non-obvious vehicles for corrupt payments
- Clinical trials integral to the business; cannot be banned
- Number of truly exceptional clinical investigators in many non-US markets is limited; these doctors likely also have key official roles
- Stringent regulatory regime governing US clinical trials gives rise to incentives to conduct clinical trial off-shore
- Cost factors may drive clinical trials in overseas markets, increasing internal company demand to conduct such trials
- Countries in which registration follows relatively automatically upon US FDA approval can require local trials on short notice

Overview

- The US Anti-Bribery Enforcement Environment
- The UK Anti-Bribery Enforcement Environment
- Clinical Trials and Compliance

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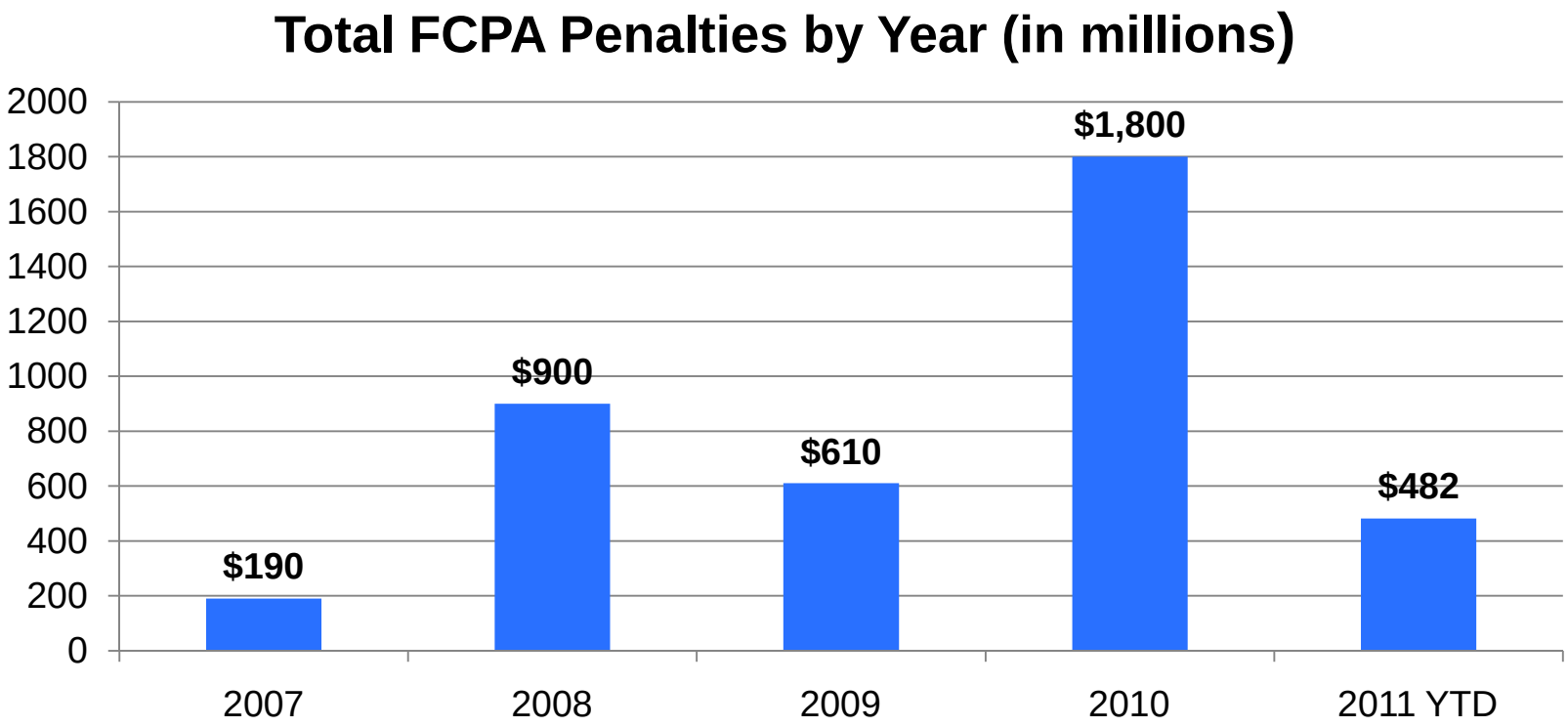
The US Anti-Bribery Enforcement Environment

Top 10 US Anti-Bribery Enforcement Trends

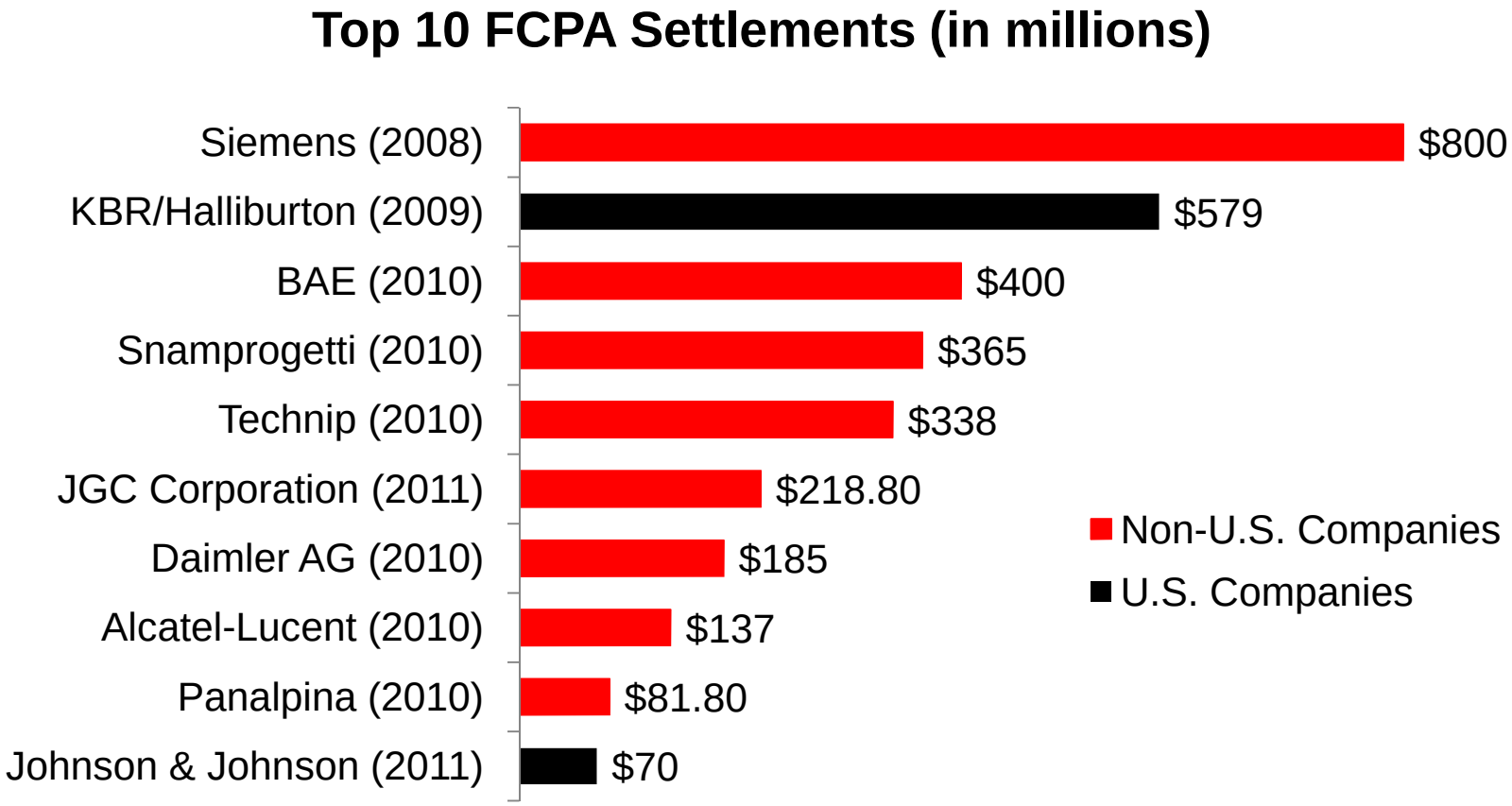
1. Large financial penalties
2. Increased prosecution of non-US companies
3. Increased prosecution of individuals
4. Definition of “foreign official”
5. Aggressive enforcement tactics
6. Aggressive and untested theories of liability
7. Increased international cooperation
8. Whistleblower provisions of the Dodd-Frank Act of 2010
9. Self-disclosure and cooperation
10. Industry-wide sweep investigations

Trend 1
Large Financial Penalties

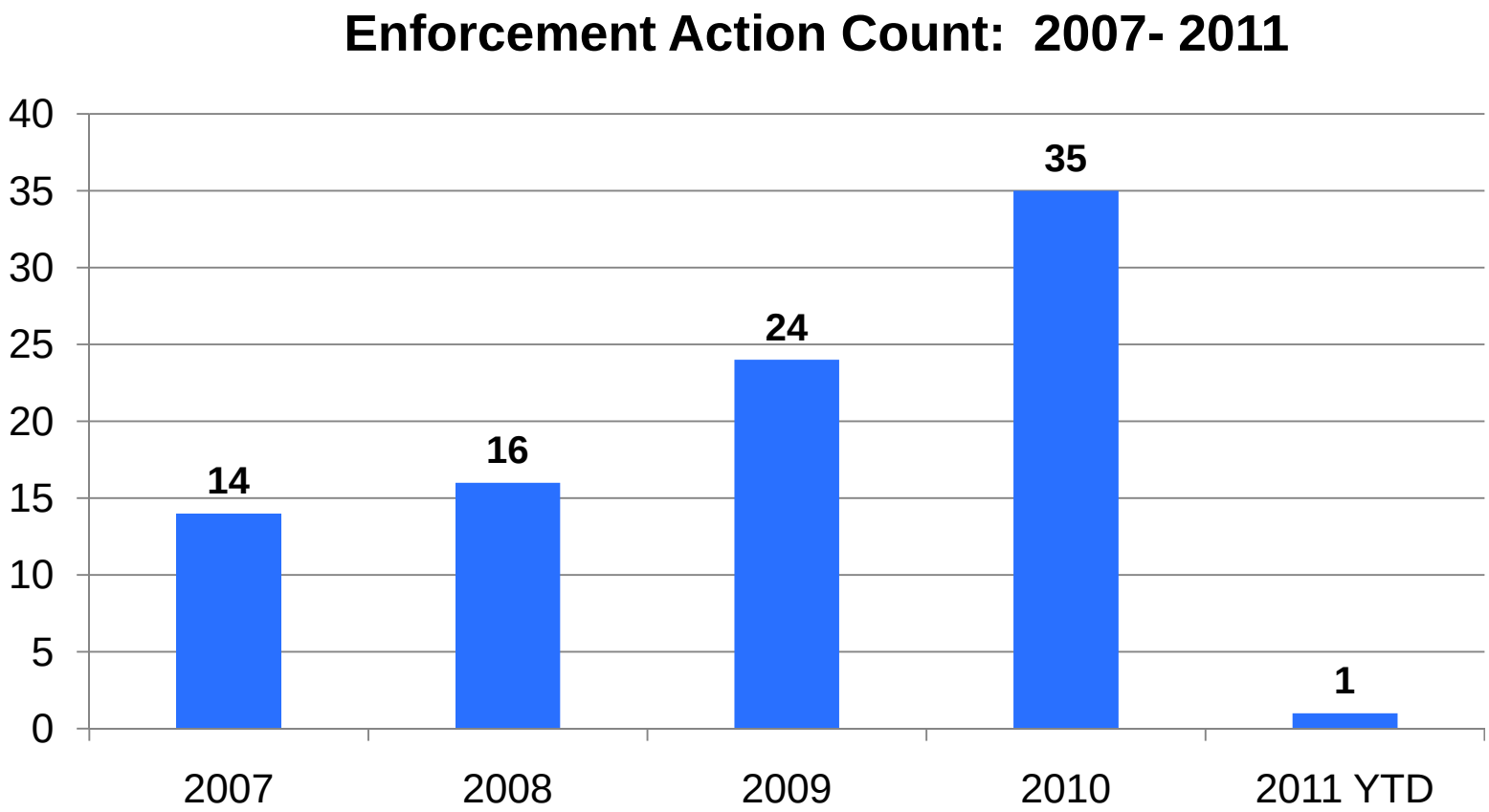
- Large criminal fines and civil penalties reaching hundreds of millions of dollars



Trend 2
Increased Prosecution of Non-US Companies



Trend 3
Increased Prosecution of Individuals



Trend 4
Definition of "Foreign Official"

- Courts agreeing with the DOJ's interpretation that employees of state-owned entities are "foreign officials" under the FCPA. A decision in an additional case remains pending.
  - *US* v. *Nguyen* (E.D. Pa. 2009)
  - *US v. Esquenazi* (E.D. Fla. 2010)
  - *US* v. *Carson* (C.D. Cal. 2011)
  - *US* v. *Aguilar* (C.D. Cal. 2011)
  - *US* v. *O'Shea* (S.D. Tx. 2011) (pending)
- Example: Doctor of a government-owned hospital.

Trend 5
Aggressive Enforcement Tactics

- "African Sting" case (2010)
  - 22 defendants in military products industry arrested in massive sting operation, using 150 FBI agents, wiretaps, a cooperating witness, and undercover agents posing as agents of foreign government officials
- Charles Jumet, president of Ports Engineering Consultants Corporation, given longest prison term in an FCPA case: 87 months imprisonment, three years supervised release, and a US$15,000 fine
- Jeffrey Tesler, a UK citizen, extradited, pleaded guilty, and agreed to forfeit a record-setting US$148,964,568

Trend 5
Aggressive Enforcement Tactics

- Guilty verdict against Lindsey Manufacturing, executives, and agent
  - The prosecution of Aguilar, a Mexican resident, arrested while in the US on business, was viewed as a strong-arm tactic to reach her fugitive husband, Enrique Faustino Aguilar Noriega

Trend 6
Aggressive and Untested Theories of Liability

- *Tenaris S.A.* (Tenaris) (2011)
  - SEC and DOJ alleged jurisdiction under the FCPA based on a single wire transfer through an intermediary bank in the US
  - Jurisdictional reach of FCPA has never been challenged in court
  - The Tenaris enforcement action is also noteworthy because it marks the SEC's first-ever use of a deferred prosecution agreement

Trend 6
Aggressive and Untested Theories of Liability

- *Panalpina Word Transport (Holding) Ltd.* (Panalpina) (2010)
  - Panalpina and its US subsidiary, Panalpina Inc. charged as an "agent" of its US-listed customers, Shell Nigeria Exploration and Production Co. Ltd., Tidewater Marine International, Inc., Transocean, Inc., Pride International, Inc., GlobalSanteFe Corp., and Noble Corp.
- *Snamprogetti Netherlands B.V.* (Snamprogetti) (2010)
  - SEC alleged that Snamprogetti, a subsidiary of foreign issuer ENI S.p.A. (an Italian company), violated the FCPA's anti-bribery provisions
  - SEC alleged jurisdiction on the basis that Snamprogetti acted as an "agent" of ENI, without alleging any facts that ENI directed or controlled Snamprogetti's decision to pay bribes

Trend 7
Increased International Cooperation

- *Innospec Inc.* (2010)
  - The DOJ, the SEC, the US Treasury Department's Office of Foreign Assets Control, and the UK's Serious Fraud Office (SFO) worked together to reach a US$40.2 million global settlement concerning US$1.5 million in bribes, in the form of cash and travel, to officials of the Iraqi Ministry of Oil
- *BAE Systems PLC* (BAE) (2010)
  - In a coordinated US and UK settlement, BAE was ordered to pay a US$400 million criminal fine and institute various remediation measures. BAE also settled with the SFO for £30 million
- Johnson and Johnson (April 2011)
  - J and J settled with DOJ, SEC, SFO and Greek Authorities. The penalty, civil sanction and civil recovery include or concern the same unlawful conduct, carried out in Greece and as such represent a global sanction.

Trend 8
Dodd-Frank Act of 2010

- Whistleblower provisions under Section 922 of the Dodd-Frank Act:
  - "Original information" to the SEC
  - Leads to an SEC enforcement action where a monetary penalty, disgorgement and prejudgment interest of US$1 million or more was imposed
  - 10 to 30 percent of the total penalties imposed must be provided to a qualified whistleblower
  - Applies to offenses committed before the statute was enacted

Trend 9
Self-disclosure and Cooperation

1. No mandatory FCPA disclosures
2. Federal securities laws
3. Sarbanes-Oxley Mandatory Disclosure, 15 U.S.C. § 78j-1
4. *In re Caremark International, Inc.*
5. Foreign law often requires disclosure
6. Pros
7. The Filip Memoranda
8. The Seaboard 21A Report
9. The Sentencing Guidelines
10. The Dodd-Frank Act
11. Cons

Trend 10
Industry-Wide Sweep Investigations

- Coordinated enforcement activity over the past few years, highlighted by last year's successful campaign against Panalpina and six companies in the oil and gas industry, demonstrates that the government has honed its blueprint for conducting industry-wide investigations
  - Pharmaceutical and medical devices (Johnson & Johnson, Merck & Co. Inc, Eli Lilly and Co.)
  - Telecommunications (Alcatel-Lucent, Haiti Teleco, Comverse Technology, Inc., Latin Node, Inc., Veraz Networks, Inc.)
  - Oil and gas (Panalpina, Bonney Island, Hercules Offshore, Inc.)

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UK Enforcement Environment

UK Bribery Act

- Section 1 and 2 BA—Liability could arise if you offer, promise, request, give, receive, or accept a financial or other advantage and you intend the advantage to induce or reward a person to perform improperly a relevant function or activity.

- Section 6 BA—If you bribe a FPO with the intention of obtaining or retaining a business advantage, you will be liable unless you can show that the action was permitted by the written law of that territory.

UK Bribery Act

- Section 7 BA—A corporate will commit an offence if bribery occurs within its organization and it does not have adequate procedures in place to prevent bribery.

Extraterritoriality

- Applies to individuals that are ordinarily resident in the UK. It is not limited to nationality.

- Applies to business that can be determined as “carrying on a business” in the UK.

Adequate Procedures

- Guidance issued in March 2010 by the MOJ.
- Prescriptive language is not used.
- Identifies six “guiding” principles:
  - Proportionate procedures
  - Top-level commitment
  - Risk assessment
  - Due diligence
  - Communication (including training for staff)
  - Monitoring and review

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Clinical Trials and Compliance

Clinical Trials and Corruption Risk

- Key area of evaluation in DOJ/SEC/SFO initiative
- Developments in anti-corruption enforcement programs
  - UK Bribery Act significantly increases risk
  - Focus on individuals, additional resources
  - US Financial Services reform – whistleblower provisions
- US Regulatory activity impacting clinical trials
  - Patient Protection and Affordable Health Care Act, P.L. 111-148, section 6002 includes Physicians Payment Sunshine Act
  - Corporate Integrity Agreements (CIAs) driving disclosure

Clinical Trials and Corruption Risk

- Non-corrupt payments to clinical investigators, including foreign officials, for genuine work performed do not violate the FCPA or, generally, other OECD-nation laws
- Corrupt payments to such officials can violate the FCPA, UK Bribery Act and other anti-corruption laws, provided jurisdiction exists
- Corrupt payments are those intended to induce the official to breach her or his duty to act in the interests of her or his employer or others (*e.g.*, patients or health care funds)
- Intent of the payor governs; violation is complete upon making of offer

Risky Business – What to Look For

- Clinical trial coordinators and teams chosen by marketing personnel instead of by medical/research staff
- Any other evidence that prescribing behavior is taken into account when decision is made to engage the investigator
- Local market personnel can sponsor trials or studies (either pre-approval or post-marketing) without notice to or approval by parent company headquarters medical staff
- Inadequate or weak due diligence and visibility into role of clinical trial investigators in official/governmental roles
- Payments to individual investigators instead of institutions
- Lack of approvals by local hospital, university, peer review or other applicable Independent review boards

Risky Business – What to Look For

- Lack of fair-market value analysis for payments
- Payments made through intermediaries that provide no distinct value added or other legitimate role in the transaction
- Lack of publishable data arising out of the study
- Other grounds for concern, including requests by an official exercising discretionary authority in one realm to be hired or to have others hired for clinical trial work, Evidence of parceling of payments to avoid limits of authority, Payments routed through bank secrecy jurisdictions, or Payments to investigators in high-risk jurisdictions

Aligning Global Compliance

- Periodic risk assessments to identify world-wide risks
  - Reviewing the "big picture" of the company's business
    - Imminent loss of patent protection as a risk factor
    - Devoting audit resources to results "too good to be true"
  - Reviewing the "small details" and their compliance impact
    - The impact of compensation systems on compliance
- Five-point framework of internal controls
  - Tone at the top
  - Formulation of clear and understandable policies
  - Local implementation and training on policy mandates
  - Testing, data mining and internal audits to uncover violations
  - Remediation, including employee discipline and retraining

Aligning Global Compliance

- Adherence to the Company's core mission statement at all levels through general leadership and detailed guidance
  - Tone from the "middle" as well as "tone from the top"
- Utilizing, whenever feasible, recommended "best practices"
  - PhRMA October 1, 2009 Guidelines for Clinical Trials
    - www.phrma.org/clinical_trials
  - OECD February 18, 2010 Council Recommendations and Annex II "Good Practice Guidance on Internal Controls"
    - www.oecd.org/dataoecd/11/40/44176910.pdf
  - Other national codes

Clinical Trial Anti-Corruption Program

- Protocols to ensure identification and compliance with local law, and local research institution regulations and industry guidelines
- Pre-study review of study design by qualified researchers; appropriate notice and/or approval of studies by headquarters
- Researchers chosen by medical/scientific staff, not marketing
- Fair-market analysis for payments to physicians
- Documented due diligence on possible conflicts of interest by potential investigators and general qualifications
- Payments made to institutions, not individuals, whenever feasible
- Execution of representations/warranties by research team
- Approvals of superiors and local supervisory bodies
- Close monitoring of and strict limits on related travel/per diem

Clinical Trial Anti-Corruption Program

- Parent company headquarters sign-off: Is it always necessary?
- Identifying government physicians and scopes of practice
- Locating/enforcing local regulations governing conflict of interest
- Identifying appropriate level of approvals by local superiors of government-employed physicians and scientific researchers
- Calculating fair market value for research services
- Cases in which company medical staff has marketing role
- Cases in which company marketing employee has genuine knowledge about the team's scientific qualifications
- Preventive steps in connection with studies that, by design, will not meet scientific gold standards but still may provide useful data

Thank You

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