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Shedding Light on the U.S. and French Sunshine Laws

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Overview of Discussion

- Origins and implementation dates
- View from 30,000 feet: what do the acts require?
- Specifics: what items are included/excluded?
- Current thorny issues in implementation
- The future

Origins and Implementation Dates – United States

- Fomenting by Sen. Charles Grassley (R-IA)



Origins and Implementation Dates – France

- A law enacted in an unprecedented hurry by former President Nicolas Sarkozy's government due to two health care scandals



View from 30,000 Feet – United States

- Drug and device manufacturers report:
 - Payments and transfers of value to *physicians* and *teaching hospitals*
 - Physician ownership of and investment interests in the manufacturers
- Definition of manufacturer
- Special rules for distributor arrangements
- Types of payments: all direct and indirect

View from 30,000 Feet – France

- Manufacturers operating in France have reporting obligations on a much broader list of (Health Care Professionals) HCPs than in the United States
- Must also identify the nature of the agreements they sign with such HCPs in order to know what data they need to disclose
- Must report to several authorities, comply with data protection regulations, and ensure compliance regarding cosmetics products

Specifics: What Items are Included – United States

- Charitable contributions
- Food and beverage
- Speaker fee compensation
- Consulting fees
- Honoraria
- Gifts and entertainment
- Travel and lodging
- Education
- Royalties or licenses
- Current and prospective ownership or investment interests
- Grants
- Research
- Space rental/facility fees

Specifics: What Items are Excluded – United States

- Existing personal relationships
- Payments or transfers of value of less than \$10 (unless annual value aggregates to \$100)
- Educational materials that directly benefit patients or are intended for patient use
- Discounts and rebates
- In-kind items for the provision of charity care to patients
- Publicly traded fund payments
- Product samples
- Short-term (less than 90 days) loans of equipment or supply of disposable/single-use devices
- Contractual warranty
- Covered recipient acting as patient
- Provision of health care
- Nonmedical professional services
- Payments for physicians furnishing services as part of legal proceedings

Specifics: What Items are Included – France

- Every benefit in kind or in cash, direct or indirect
- Charitable contributions
- Food and beverage
- Gifts of small value
- Travel and lodging

Specifics: What Items are Excluded – France

- Benefits of value of less than **€10 VAT incl.**
- Payments made as contractual remuneration, such as speaker fees or consulting fees
- Payments made for commercial sales for goods and services
- Companies manufacturing or marketing cosmetic products, contact lenses, and tattoo products need only report clinical trial agreements or agreements related to safety evaluation and vigilance. Therefore, all other agreements can be excluded.

Special U.S.-specific Rules (no French counterparts)

- Research payments
- Ownership/investment interests
- Dispute resolution

Special France-specific Rules (no U.S. counterparts)

- Data protection
- Specific format set forth by the French Data Protection Authority CNIL for online disclosure
- HCPs must be notified by the companies that they will disclose their related data on the French unique state portal for transparency purposes
- No prior notification obligation to the CNIL necessary unless disclosed data is transferred to the United States, or to any other country not offering adequate data protection according to EU regulation

Penalties – United States

- Civil monetary penalties (CMPs) of \$1,000 – \$10,000 for each instance of non-reporting, up to a maximum of \$150,000
- Knowing failure to report is subject to CMPs of \$10,000 - \$100,000, up to a maximum of \$1 million
- CMPs for failure to report and knowing failure to report can be aggregated to a maximum of \$1,150,000

Penalties – France

- A fine of up to €45,000 and additional sanctions
- The publication of the judicial decision relating to the conviction
- The prohibition of the manufacture, packaging and import of any health product

Current Thorny Issues in Implementation – United States

- Indirect payments
- Systems/data issues, including rejection of data
- New proposed regulations
- Dispute resolution

Current Thorny Issues in Implementation – France

- The first semester of 2014 has been released on the unique state portal:
 - 779.207 benefits
 - 323.985 agreements
 - 1.103.192 new data
- 77,44 percent of the declarations are related to drugs
- More than 1,130 companies are registered on the unique state portal

The Future – United States

- Some are same as current issues:
 - How to incorporate new regulations into current systems
 - Dispute resolution
- Lack of context in presentation of payment data may lead to public misunderstandings
- Reluctance by some physicians to undertake research, participate in training, etc.
- Fueling the qui tam plaintiffs' bar

The Future – France

- A project of decree would slightly modify the schedule of declaration of the agreements.
- Agreements would need to be declared every six months, as benefits, instead of a declaration two weeks after its conclusion.
- Even though there are transparency obligations in both the EU and the United States, it is not necessarily possible to use data from one side for the other



Questions?

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**Thank You
Merci**

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