

## THE PRACTICAL REALITIES OF ANTI-KICKBACK AND STARK ENFORCEMENT

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### Why Bad Things Can Happen to Good People in Health Care Enforcement

- Laws are not enforced by the people that wrote them.
- Laws are ambiguous – often easy to state, but hard to apply.
- Regulation by prosecution has become the norm in health care.

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### *Wall Street Journal* Got it Right

April 9, 2008 - OPINION

- “Making Business a Crime”
- “These creative theories rarely get tested in the courts, because federal criminal sentences are so draconian that the overwhelming majority of defendants – including those who have committed no crime – enter into plea bargains. Thus, the federal prosecutor's ability to indict the proverbial ham sandwich readily leads to guilty findings without appellate review. Even those cases that make it to an appellate court often get affirmed by a judiciary that is increasingly complicit in the DOJ's law-as-silly-putty approach.”

[Commenting on TAP case – Company pled, individuals acquitted]

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### Practical Realities (How to Avoid Bad Things Happening to Good People)

- Understand the perspective of the enforcers.
- Recognize that biggest opportunities to prevent and create problems are at the top.
- Create larger margins of error, due to lack of bright lines.
- Must watch your words as well as your steps.

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### Understand the Government's Perspective

- They do not view actions the same way you do.
- Do not assume they see your white hat.
- Not safe just because you are "out in the open."

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### AKS and Stark Investigations Focus on Senior Management More than Others

- Conduct that carries the highest risks often within control of senior management.
- Witnesses and documents will come from ranks of senior management.
- Need to lead by example, as well as create a culture of compliance.

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### Need to Operate with Large Margin of Error

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- Highway mentality can be fatal.
- Remember regulation by prosecution.
- There are no bright lines.

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### There are no Bright Lines Because:

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- These are state-of-mind crimes.
- Bad intent can negate good intent.
- Corporate intent is collective.
- Bad intent of others can be contagious.
- Intent is not always knowable without hindsight.

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### Watch Your Words as Well as Your Steps

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- No such thing as “off the record” conversations.
- Almost infinite opportunities to misspeak.
  - Email lives forever.
  - PowerPoint decks do too.
  - Hallway conversations.
- Not always possible to unring the bell.

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## It Is Not Just Institutions That Are At Risk

According to a March 4, 2009 *New York Times* Article

- Within a few months, federal officials "plan to file civil and criminal charges against a number of surgeons" who allegedly "demanded profitable consulting agreements from device makers in exchange for using their products."

**"What we need to do is make examples of a couple of doctors so that their colleagues see that this isn't worth it."**

Lewis Morris, Chief Counsel to the Department of Health and Human Services Office of Inspector General

The New York Times

March 4, 2009  
**Prosecutors Plan Crackdown on Doctors Who Accept Kickbacks**

WASHINGTON — Federal health officials and prosecutors, frustrated that they have been unable to stop illegal kickbacks to doctors from drug and device companies, are investigating doctors who take money for using those products.

For years, prosecutors rarely pursued doctors because they believed that justice would sympathize with respected clinicians. But within a few months, officials plan to file civil and criminal charges against a number of surgeons who they say demanded profitable consulting agreements from device makers in exchange for using their products.

"What we need to do is make examples of a couple of doctors so that their colleagues see that this isn't worth it," said Lewis Morris, chief counsel to the inspector general of the Department of Health and Human Services. "We want to send the message to the physician community — particularly surgeons — that you can't do this."

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## Seeing the World Through Their Eyes

- View every deal with skepticism – because the Government will.
- But don't become cynical just because the Government has.

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## Lessons – Optics and Letter of Law Matter

- Consider Government's skeptical perspective.
  - Avoid the sidelines.
  - Avoid the highway.
- Avoid ambiguity - document good intent when considering proposals and making decisions.
- Avoid e-mail "wars," and think before you hit the "send" button.

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### Stark Problems (for the pure of heart)

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- Deluge of Technical Problems is Common.
- The Cure is Becoming Worse Than the Disease.
- The Recent OIG "Open Letter" Made the Problems Worse.

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### Conclusion & Questions

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