

# Healthcare and FDA Compliance in 2025

## Litigation Insights & Real-World Strategies

February 13, 2025



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AN FDA LAW FIRM

**Fredrikson**

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# Welcome



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# Agenda

9-9:45 a.m.

Litigation Insights: FDA War Stories from the Front Lines

9:45-10:30 a.m.

Practical Tips for Improving Your Compliance

10:30-10:45 a.m.

Break

10:45-11:30 a.m.

Turning Plans into Practice

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# Litigation Insights: FDA War Stories from the Front Lines



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# Agenda

- Who are you dealing with?
- What kind of legal proceeding is it?
- Preparing the Company?
- What does “winning” look like?

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# Who are you dealing with?

- Is it a federal agency?
- Is it the Department of Justice?
- “Relators” and “Whistleblowers”?
- State Agencies?

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# What kind of legal proceeding is it?

- Administrative Procedures Act in Play
- Specific Agency Procedures
- Procedures for Appeal
- Referral to AG or DOJ/OIG – civil and criminal

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# Preparing the Company

- Know the risks
- Identify key witnesses and documentation
- Prepare compliance policies
- Coach employees on proper documentation
- Do employees need their own lawyer?



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# What does “winning” look like?

- Avoid issue creep
- Concluding the investigation
- Settling any claims
- Litigation if no better option
- Consider collateral consequences
- Clearly define Compliance going forward

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# Questions

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# Presenters



**Joseph Dixon**  
Fredrikson  
Shareholder



**David Graham**  
Gardner Law  
Senior Counsel

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# Practical Tips for Improving Your Compliance



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# Agenda

- Compliance program basics
- False Claims Act enforcement update
- Practical tips & best practices
- How to prepare for an unexpected visitor
- Questions

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# Elements of an Effective Compliance Program

1. Written policies and procedures
2. Compliance leadership and oversight
3. Effective training and education
4. Effective lines of communication with the Compliance Officer and Compliance Hotline
5. Enforcing standards: consequences and incentives
6. Risk assessment, auditing, and monitoring
7. Responding to detected offenses and developing corrective action initiatives

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# False Claims Act Enforcement Update FY 2024

- Total Settlements & Judgments: \$2.9 billion
- Number of Qui Tam Lawsuits: 979 (*highest in history*)
- Total Settlements & Judgments Since 1986: \$78 billion
- Total Cases Resolved: 558 (*2nd highest after 2023's record of 566*)

# FCA Enforcement



Category	FY 2023	FY 2024
Total FCA Recoveries (\$B)	2.68	2.9
Total Qui Tam Lawsuits Filed	712	979
Total FCA Settlements & Judgments	543	558
Qui Tam Recoveries (\$B)	2.3	2.4
Whistleblower Payouts (\$M)	349	400



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# DOJ Priorities

- Health Care Fraud (*Largest sector*)
  - Opioid Crisis & Pharmaceutical Fraud
  - Medicare Advantage fraud
  - Kickback, Stark Law
- Pandemic Relief Fraud
- Cybersecurity & Government Contracts Fraud
- Military Procurement Fraud
- Whistleblower Incentives & Qui Tam Actions

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# Hot Topics

- Opioids
- Lack of medical necessity
- Unnecessary services
- Medicare Advantage
- Kickbacks
  - HCP payments over FMV
  - Luxury trips, lavish meals
  - Speaker programs

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# Lessons

- Whistleblower risk is at an all-time high
  - Strengthen internal compliance and reporting programs
  - Detect fraud before a whistleblower does
- Healthcare enforcement is not slowing down
- Cybersecurity compliance is now a major FCA risk area
- Expect continued aggressive enforcement against improper billing, kickbacks, and unnecessary services

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# How to Adapt Your Compliance Program

- Compliance policy gap assessment
- Create an effective internal reporting system
- Regular compliance training
- Internal audits & monitoring (focus on Hot Topics)
- Address & correct issues quickly
- Hold leadership accountable
- Monitor enforcement trends

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# Self-Disclosure: Is honesty the best policy?

- Risks of Disclosing:
  - DOJ could expand into other areas
  - Can't go back
  - No guarantee
  - Risk of uncovering additional issues
- Risks of Not Disclosing:
  - Enforcement agencies discovering misconduct
  - Whistleblower risk
  - Penalties may be more severe

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# What is Compliance?

- Doing what is right?
- Doing whatever the government says?



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# What is Compliance?

- Doing what is right?
- Doing whatever the government says?
- Doing what's legal?
- Something else I haven't thought of?



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# The Problem

- An employee presents with a compliance concern. “But I heard that’s illegal.”
- You need to evaluate the concern and, if appropriate, dissuade them
- Law and psychology merge

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# There's a Billy Joel Song for That!

- Assessing the individual's credibility
  - Listen with an open mind
  - Do you have an employee who cries wolf?



"Wait a minute! Isn't anyone here a real sheep?"

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# There's a Billy Joel Song for That!

- Assessing the individual's credibility
  - Listen with an open mind
  - Do you have an employee who cries wolf?
  - The stopped clock axiom

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# Choose Wisely

- You can only persuade the persuadable
- Power of coffee
- How much thought have you given to your interviewing process?
- “Name that whistleblower”

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# Aha!

- Is it better to take things under advisement?
- Be sure to ask for citations to authority

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# Regulatory Hierarchy

- Constitution (due process, contracts clause, enumerated powers)
- Statutes (U.S. Code/Social Security Act)
- Regulations/National Coverage Determinations
  - Code of Federal Regulations
  - State Regulations or Administrative Code
  - NCD Manual (A binding manual!)

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# Regulatory Hierarchy

- Everything else is nonbinding
  - Manuals
  - Local coverage determinations
  - Guidance from contractors
  - Regulatory Preambles
  - FAQs



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# SSA 1871(a)(2) is Our Friend

- “No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this title shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).”

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# Manuals/Guidance Can't Limit Coverage

- “Thus, if government manuals go counter to governing statutes and regulations of the highest or higher dignity, a person ‘relies on them at his peril.’ ” Government Brief in Saint Mary’s Hospital v. Leavitt.
- “[The Manual] embodies a policy that itself is not even binding in agency adjudications.... Manual provisions concerning investigational devices also ‘do not have the force and effect of law and are not accorded that weight in the adjudicatory process.’ ” Gov’t brief in Cedars-Sinai Medical Center v. Shalala.

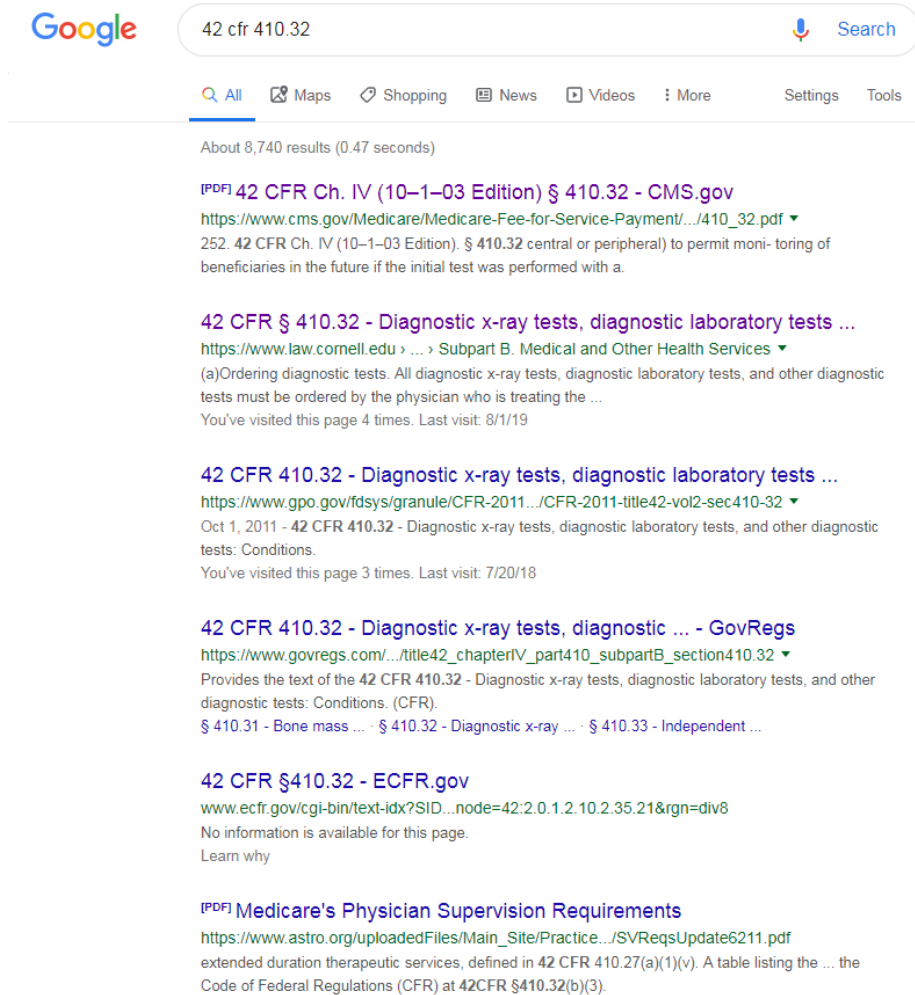
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# Role of LCDs

- An LCD is a coverage determination issued by a contractor, not promulgated by the agency, and is not even binding on an administrative law judge. See 42 C.F.R. 405.1062(a).
- “The district court correctly stated in its instructions to the jury that LCDs are ‘eligibility guidelines’ that are not binding and should not be considered “the exact criteria used for determining” terminal illness.”
  - *United States v. Aseracare, Inc.*, et al., 938 F.3d 1278, 1288 (11<sup>th</sup> Circ. 2019)



# Google With Caution!



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42 cfr 410.32

Search

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About 8,740 results (0.47 seconds)

**[PDF] 42 CFR Ch. IV (10–1–03 Edition) § 410.32 - CMS.gov**  
[https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/.../410\\_32.pdf](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/.../410_32.pdf) ▼  
252. 42 CFR Ch. IV (10–1–03 Edition). § 410.32 central or peripheral) to permit monitoring of beneficiaries in the future if the initial test was performed with a.

**42 CFR § 410.32 - Diagnostic x-ray tests, diagnostic laboratory tests ...**  
<https://www.law.cornell.edu> > ... > Subpart B. Medical and Other Health Services ▼  
(a)Ordering diagnostic tests. All diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the ...  
You've visited this page 4 times. Last visit: 8/1/19

**42 CFR 410.32 - Diagnostic x-ray tests, diagnostic laboratory tests ...**  
<https://www.gpo.gov/fdsys/granule/CFR-2011-.../CFR-2011-title42-vol2-sec410-32> ▼  
Oct 1, 2011 - 42 CFR 410.32 - Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.  
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**42 CFR 410.32 - Diagnostic x-ray tests, diagnostic ... - GovRegs**  
[https://www.govregs.com/.../title42\\_chapterIV\\_part410\\_subpartB\\_section410.32](https://www.govregs.com/.../title42_chapterIV_part410_subpartB_section410.32) ▼  
Provides the text of the 42 CFR 410.32 - Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions. (CFR).  
§ 410.31 - Bone mass ... - § 410.32 - Diagnostic x-ray ... - § 410.33 - Independent ...

**42 CFR §410.32 - ECFR.gov**  
[www.ecfr.gov/cgi-bin/text-idx?SID...node=42:2.0.1.2.10.2.35.21&rgn=div8](http://www.ecfr.gov/cgi-bin/text-idx?SID...node=42:2.0.1.2.10.2.35.21&rgn=div8)  
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extended duration therapeutic services, defined in 42 CFR 410.27(a)(1)(v). A table listing the ... the Code of Federal Regulations (CFR) at 42CFR §410.32(b)(3).

# The Power of the Internet?

## §410.32

central or peripheral) to permit monitoring of beneficiaries in the future if the initial test was performed with a technique that is different from the proposed monitoring method.

(d) *Beneficiaries who may be covered.* The following categories of beneficiaries may receive Medicare coverage for a medically necessary bone mass measurement:

(1) A woman who has been determined by the physician (or a qualified nonphysician practitioner) treating her to be estrogen-deficient and at clinical risk for osteoporosis, based on her medical history and other findings.

(2) An individual with vertebral abnormalities as demonstrated by an x-ray to be indicative of osteoporosis, osteopenia, or vertebral fracture.

(3) An individual receiving (or expecting to receive) glucocorticoid (steroid) therapy equivalent to 7.5 mg of prednisone, or greater, per day for more than 3 months.

(4) An individual with primary hyperparathyroidism.

(5) An individual being monitored to assess the response to or efficacy of an FDA-approved osteoporosis drug therapy.

(e) *Denial as not reasonable and necessary.* If CMS determines that a bone mass measurement does not meet the conditions for coverage in paragraphs (b) or (d) of this section, or the standards on frequency of coverage in paragraph (c) of this section, it is excluded from Medicare coverage as not "reasonable" and "necessary" under section 1862(a)(1)(A) of the Act and §411.15(k) of this chapter.

[63 FR 34327, June 24, 1998]

## §410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

(a) *Ordering diagnostic tests.* All diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not rea-

## 42 CFR Ch. IV (10-1-03 Edition)

sonable and necessary (see §411.15(k)(1) of this chapter).

(1) *Chiropractic exception.* A physician may order an x-ray to be used by a chiropractor to demonstrate the subluxation of the spine that is the basis for a beneficiary to receive manual manipulation treatments even though the physician does not treat the beneficiary.

(2) *Mammography exception.* A physician who meets the qualification requirements for an interpreting physician under section 354 of the Public Health Service Act as provided in §410.34(a)(7) may order a diagnostic mammogram based on the findings of a screening mammogram even though the physician does not treat the beneficiary.

(3) *Application to nonphysician practitioners.* Nonphysician practitioners (that is, clinical nurse specialists, clinical psychologists, clinical social workers, nurse-midwives, nurse practitioners, and physician assistants) who furnish services that would be physician services if furnished by a physician, and who are operating within the scope of their authority under State law and within the scope of their Medicare statutory benefit, may be treated the same as physicians treating beneficiaries for the purpose of this paragraph.

(b) *Diagnostic x-ray and other diagnostic tests—(1) Basic rule.* Except as indicated in paragraph (b)(2) of this section, all diagnostic x-ray and other diagnostic tests covered under section 1861(s)(3) of the Act and payable under the physician fee schedule must be furnished under the appropriate level of supervision by a physician as defined in section 1861(r) of the Act. Services furnished without the required level of supervision are not reasonable and necessary (see §411.15(k)(1) of this chapter).

(2) *Exceptions.* The following diagnostic tests payable under the physician fee schedule are excluded from the basic rule set forth in paragraph (b)(1) of this section:

(i) Diagnostic mammography procedures, which are regulated by the Food and Drug Administration.

# What's This Gibberish??

(iii) *Medical necessity.* The entity submitting the claim may request additional diagnostic and other medical information from the ordering physician or nonphysician practitioner to document that the services it bills are reasonable and necessary. If the entity requests additional documentation, it must request material relevant to the medical necessity of the specific test(s), taking into consideration current rules and regulations on patient confidentiality.

(4) *Automatic denial and manual review.* (i) *General rule.* Except as provided in paragraph (d)(4)(ii) of this section, CMS does not deny a claim for services that exceed utilization parameters without reviewing all relevant documentation that is submitted with the claim (for example, justifications prepared by providers, primary and secondary diagnoses, and copies of medical records).

(ii) *Exceptions.* CMS may automatically deny a claim without manual review if a national coverage decision or LMRP specifies the circumstances under which the service is denied, or the service is specifically excluded from Medicare coverage by law.

(e) *Diagnostic laboratory tests furnished in hospitals and CAHs.* The provisions of paragraphs (a) and (d)(2) through (d)(4) of this section, inclusive, of this section apply to all diagnostic laboratory test furnished by hospitals and CAHs to outpatients.

[62 FR 59098, Oct. 31, 1997, as amended at 63 FR 26308, May 12, 1998; 63 FR 53307, Oct. 5, 1998; 63 FR 58906, Nov. 2, 1998; 64 FR 59440, Nov. 2, 1999; 66 FR 58809, Nov. 23, 2001; 69 FR 66421, Nov. 15, 2004; 72 FR 66398, Nov. 27, 2007; 75 FR 73615, Nov. 29, 2010; 77 FR 69361, Nov. 16, 2012; 83 FR 60073, Nov. 23, 2018; 85 FR 19286, Apr. 6, 2020; 85 FR 27620, May 8, 2020; 85 FR 54871, Sept. 2, 2020]

§ 410.33 - Independent diagnostic testing facility.





Displaying title 42, up to date as of 2/04/2025. Title 42 was last amended 1/23/2025.

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ECFR CONTENT



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**EDITORIAL NOTE ON PART 410**

**Editorial Note:** Nomenclature changes to part 410 appear at [62 FR 46037](#), Aug. 29, 1997.

**§ 410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.**

- (a) **Ordering diagnostic tests.** Except as otherwise provided in this section, all diagnostic x-ray tests, diaanostic laboratory tests, and other diaanostic tests must be ordered by the phvsician who is





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# Links to Official Versions

- Current CFR: <https://gov.ecfr.io/cgi-bin/ECFR>
- Federal Register: <https://www.federalregister.gov/>
- Manuals: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/index.html?redirect=/manuals/>

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# What Will Get You On TV?

- Financial Relationships
- Billing snafus
- Coding problems
- Giving billing advice
- Off label promotion?
- Confidentiality snafus
- Pixels?
- Lying in an interaction with the government

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# Question Authority

- Is it a requirement or a guideline?
- Medicare: is it in the **constitution, statute, regulations, Medicare Claims Processing or other Manuals, or carrier policy?**
- Private payors: is it in the contract? Are the Manuals incorporated?
- Get a copy of the rule in writing
- Have your lawyer/consultant explain all arguments supporting and refuting the position
- Determine if the rule was properly promulgated
- Just because someone sounds smart doesn't mean they're right

THIS BEDROCK LIKELY FORMED  
AS THE DALMATIAN MICROPLATE  
SUBDUCTED UNDER EAST LAIKA  
DURING THE UPPER POMERANIAN.

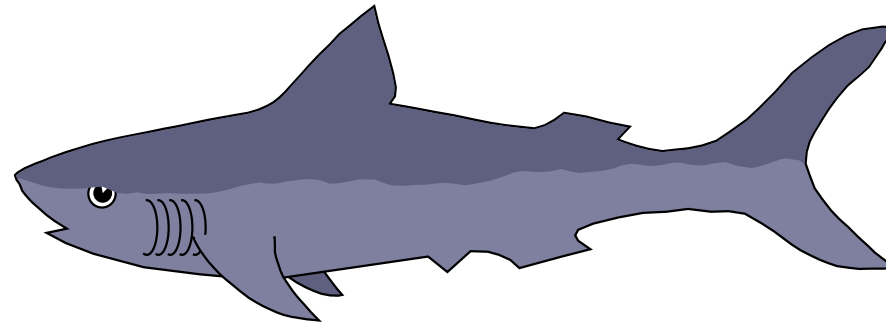


GEOLOGY TIP: THERE ARE SO MANY MICROPLATES  
AND AGES THAT NO ONE REMEMBERS THEM ALL,  
SO IN A PINCH YOU CAN BLUFF WITH DOG BREEDS.

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# Here Comes Trouble

- CMS
- OIG
- FBI
- MFCU
- Postal Inspector
- IG Railroad Retirement Board
- DCIS
- Licensing boards
- NRC
- FDA
- DEA
- FDA
- Patients



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# Prep Work Is Key

- Know what to do/who to call
- Try to remember these tips; it is easy to forget, and hard not to panic (get our laminated card)
- An emergency plan must include how to contact people at odd hours

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# The Letter

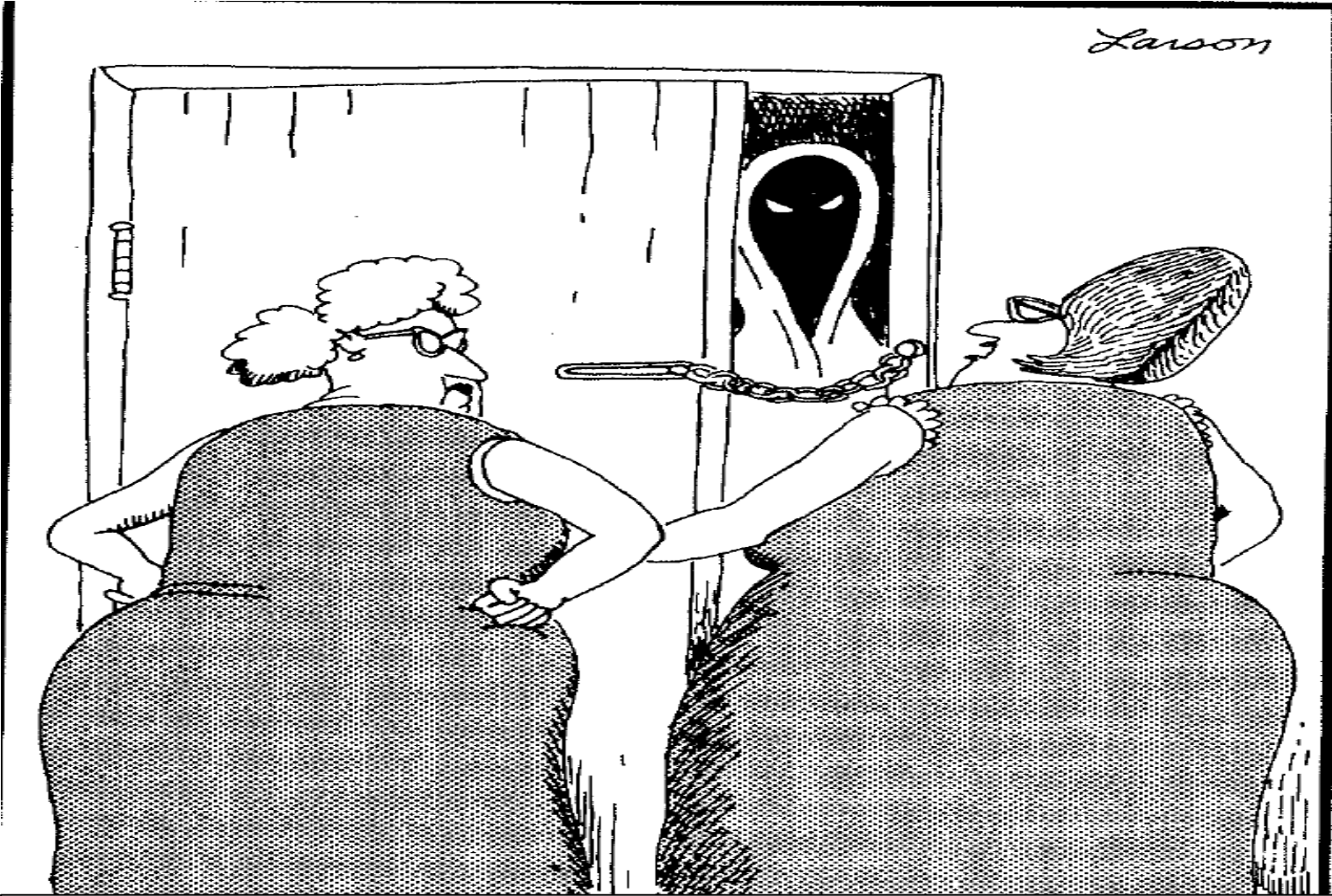
- Who sent it?
- Requests for multiple records are much more troubling
- Make sure you keep a copy of everything you send
- Be thorough
- Talk with counsel

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# Telephone Calls

- Get the caller's name
- Find out what they are talking about





“Now wait just a minute here...  
How are we supposed to know you’re the REAL Angel of Death?”

---

# Telephone Calls

- Get the caller's name
- Find out what they are talking about
- Call the person back. This will allow you to verify the caller's identity and gather your thoughts.

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# FDA Investigations

- Ask for identification and Form 482 (Notice of Inspection)
- Don't panic. Notify the internal FDA response team.
- Ask questions about the scope, escort FDA to meeting area
  - **T** – Tell the **TRUTH**
  - **L** – **LISTEN** to the question (and make sure you understand it)
  - **A** – **ANSWER** the question (clearly and concisely)
  - **S** – **STOP** after you've answered
  - **T** – Tell the **TRUTH**

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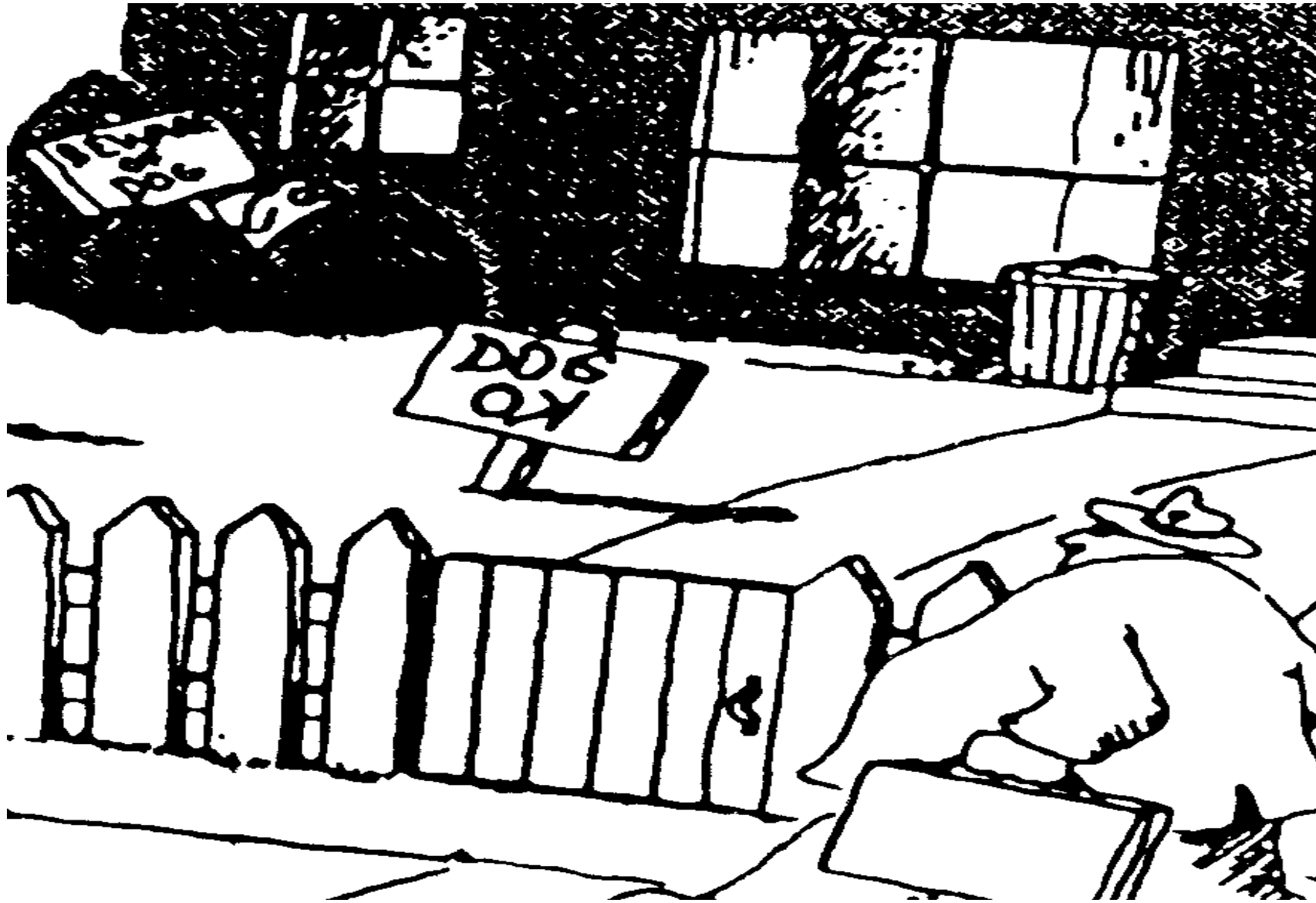
# The Subpoena

- A grand jury subpoena from Atlanta says, "The United States Attorney requests that you do not disclose the existence of this subpoena. Any such disclosure would impede the investigation being conducted and thereby interfere with the enforcement of the law."

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# Armed Agents at the Door

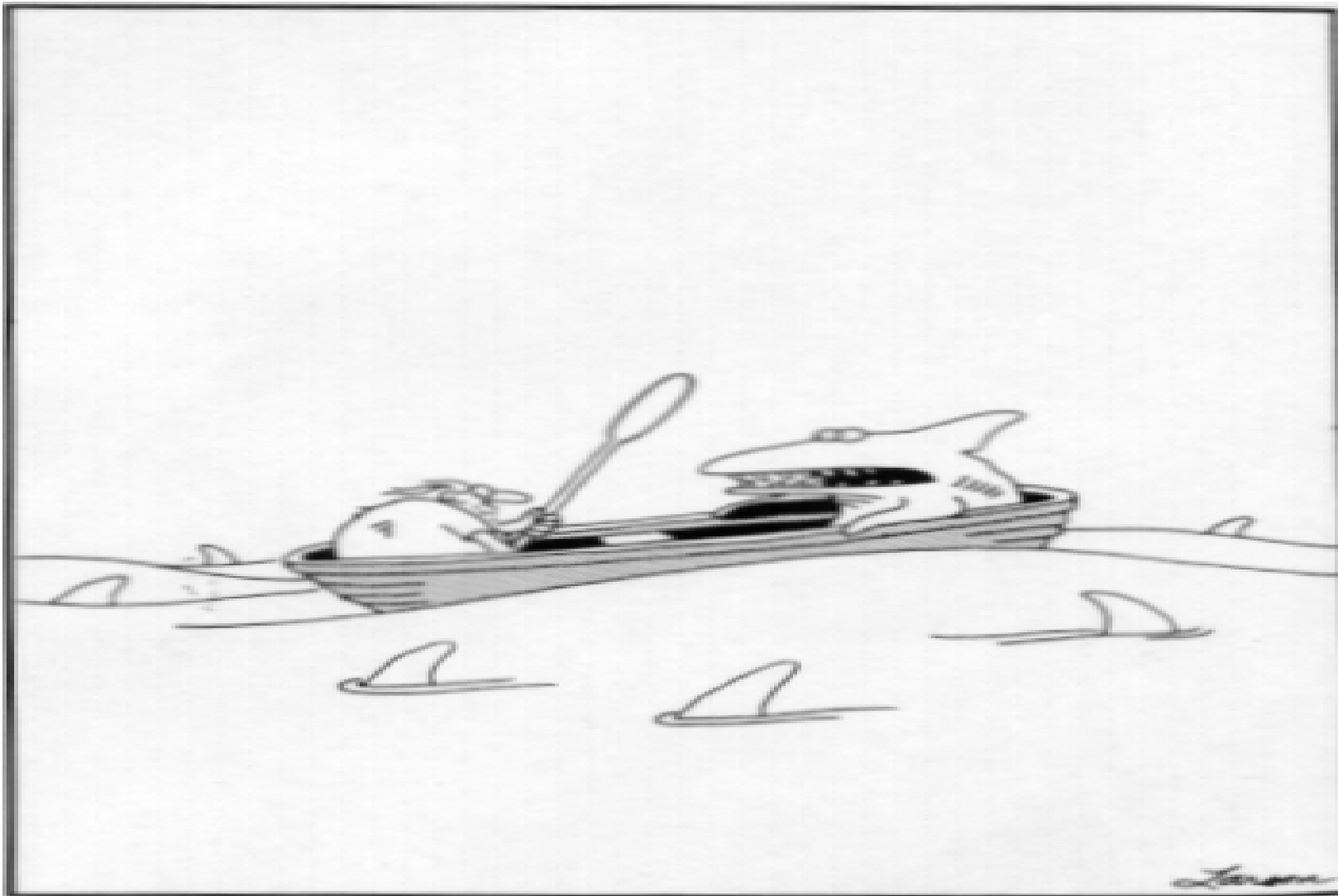
- If they have a warrant, let them in
- Do not talk to them
- Get I.D. and call a lawyer



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# Dealing With Investigations

- Agents want you to talk. They will use your:
  - Fear
  - Confidence
- Your biggest weapon:
  - Silence
- Be especially wary of saying “my lawyer told me it was ok.” You will have waived the attorney-client privilege.



“OK. I’ll go back and tell my people that you’re staying in the boat, but I warn you they’re *not* going to like it.”



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# The Agents Are NOT Your Friends:

- Don't try to convince the agent "It is all a misunderstanding."

*Remember two key points:*

- Medicare rules are complicated. You may have violated one without knowing it;
- To many investigators - there is no such thing as an "innocent mistake."

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# Know Your Rights

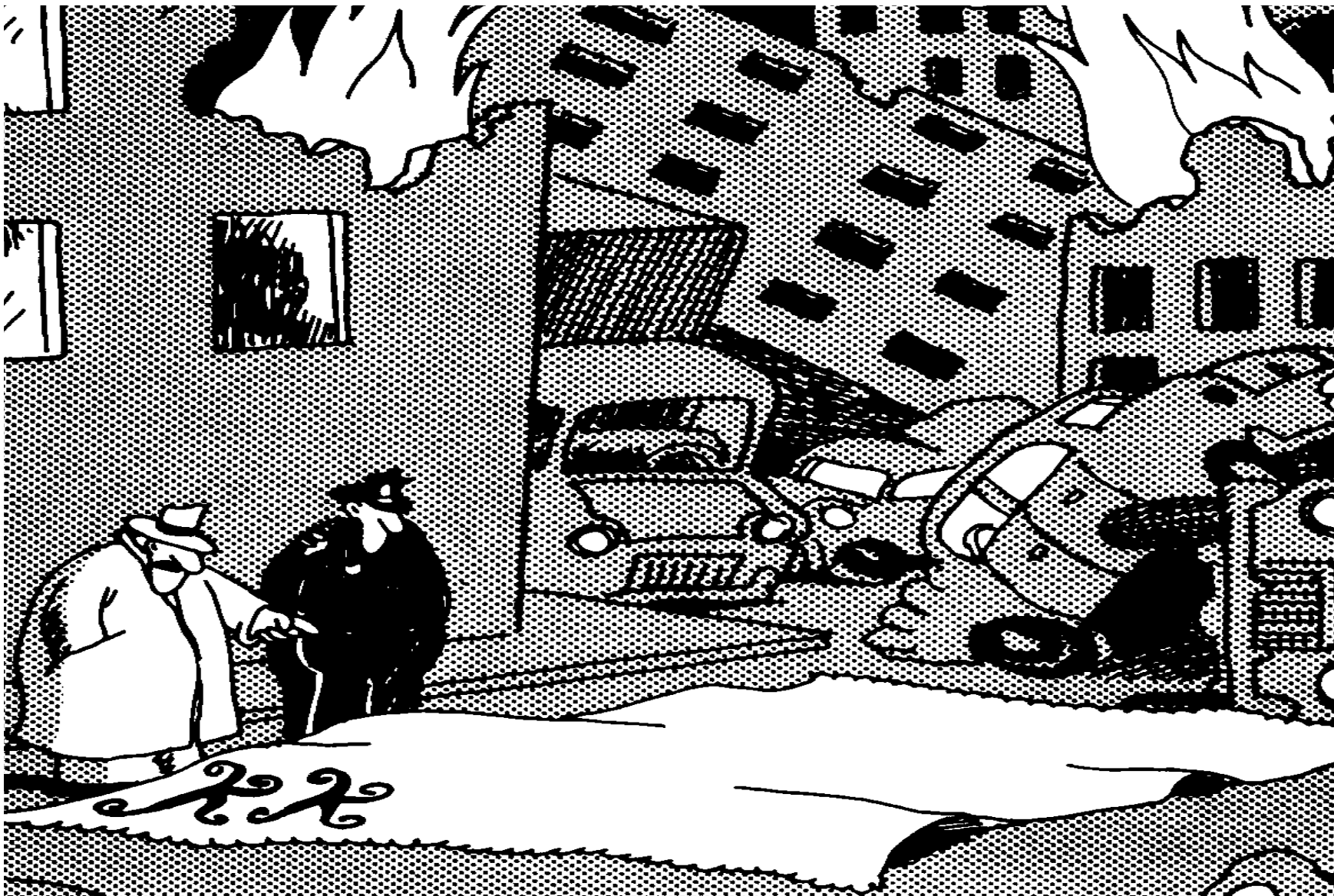
Agent:

- Can't require anyone to attend interview
- Can't obtain documents without a warrant or subpoena
- Can't obtain privileged information
- Can't prevent you from talking about the interaction

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# Know Your Obligations

- Cannot prevent employees from talking
- If you talk, you must tell the truth
- Never destroy/hide documents



**Which monster did this – Godzilla? Gargantua? Who?”**



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# Presenters



**David Glaser**  
Fredrikson  
Shareholder



**Amanda Johnston**  
Gardner Law  
Partner

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# Turning Plans into Practice



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# Panelists



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(Moderator)**

Gardner Law

Founder & Managing  
Partner



**Stephen Froehle**

Coloplast

VP & General Counsel



**Sarah Karlgaard**

FUJIFILM

General Counsel &  
Secretary



**Anne Miller**

Medtronic

Senior Strategic Counsel



**Alex Rosenstein**

NMDP

General Counsel



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# Closing Remarks



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