

Select Agent Program

Presented by:

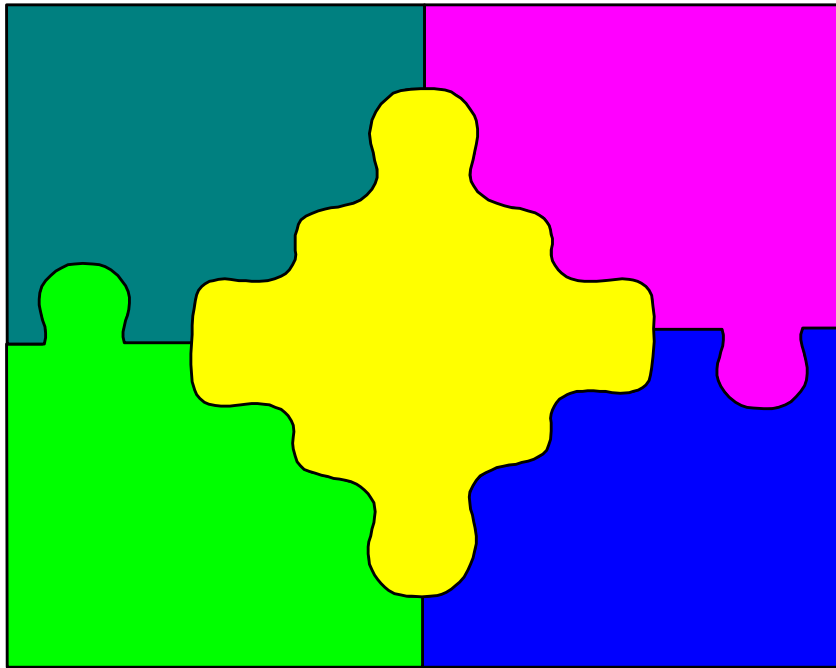
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Goldberg Legal Services

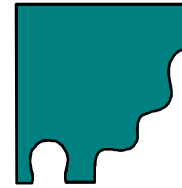
<http://selectagentlaw.com>

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Overview



- ⌘ Criminal Sanctions
- ⌘ Civil Sanctions
- ⌘ Civil Regulations
- ⌘ Enforcement
- ⌘ Holistic Compliance



Criminal Sanctions

⌘ **Penalty: Incarceration up to five years.**

⌘ **3 Violations:**

☒ A **restricted person** ships or transports select agents or toxins.

☒ A person or entity knowingly transfers a select agent or toxin to an entity or person and the sender knows, or has reasonable cause to believe that the recipient is not registered.

☒ An **unregistered** person or entity knowingly possesses a select agent or toxin.

☒ Enforcement: FBI, DOJ, U.S. Attorney.

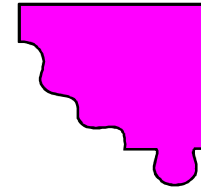
⌘ 1. Who goes to jail for a corporate violation of the program?

☒ The Act does not say.

☒ Under other criminal statutes Corporate Officers can be held criminally liable.

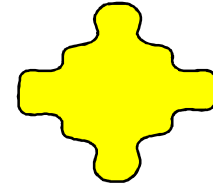
☒ The future will tell- depending on public policy and nature of violation.

Civil Sanctions



- ⌘ I. Both HHS and USDA may impose Civil Money Penalties against violators of select agent regulations.
 - ☒ The word Civil Money Penalty (or “CMP” in regulatory jargon) simply means a fine.
 - ☒ \$500,000 for each violation committed by an entity.
 - ☒ \$250,000 for each violation committed by a person.
 - ☒ There is no aggregate amount (i.e. 10 violations could mean \$5,000,000 in penalties).
- ⌘ II. Both HHS and USDA may deny or revoke registrations.
- ⌘ III. Debarment.

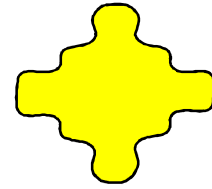
HHS Select Agent Regulations (42 CFR part 73)



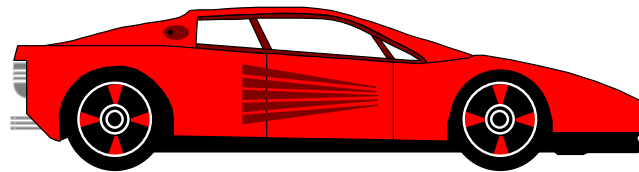
⌘ The Big 10:

☒ Registration	42 C.F.R. 73.7
☒ Responsible Official	42 C.F.R. 73.9
☒ Restricting Access	42 C.F.R. 73.10
☒ Security	42 C.F.R. 73.11
☒ Biosafety	42 C.F.R. 73.12
☒ Incident Response	42 C.F.R. 73.14
☒ Training	42 C.F.R. 73.15
☒ Transfers	42 C.F.R. 73.16
☒ Records	42 C.F.R. 73.17
☒ Notification of Theft/ Loss/ Release	42 C.F.R. 73.19

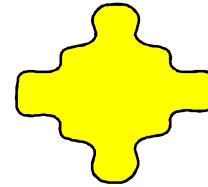
A lesson in Strict Liability



⌘ The regulations are “**strict liability**” in nature.



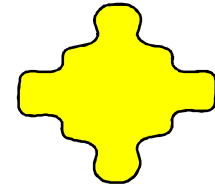
A lesson in Strict Liability



⌘ Strict Liability Offenses:

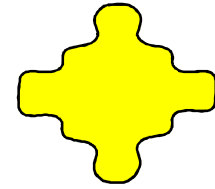
- ☑ Honest mistakes do not matter. If you violate, you are subject to a penalty.
- ☑ There are very few defenses.
- ☑ Do you have a defense or an excuse?

Misnomers about civil violations



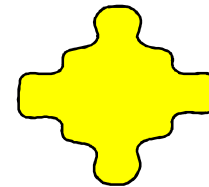
- ⌘ Would a jury really convict someone for an honest mistake?
- ⌘ The Columbo Syndrome/ Guilt beyond a shadow of a doubt.

Hot topics in compliance



- ⌘ Training (42 C.F.R. section 73.15).
- ⌘ Responsible Officials (42 C.F.R. section 73.9).

Training (73.15)



⌘ What:

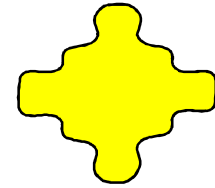
- ☒ Information and training on biosafety and security.
- ☒ Must address: 1) the particular needs of individual, 2) the work they will do, and, 3) the risks posed by select agents and toxins.

⌘ Who:

- ☒ To each individual with, or without, a SRA.

⌘ When:

- ☒ Prior to access.
- ☒ Prior to visiting areas where agents are handled or stored.
- ☒ Refresher training annually.

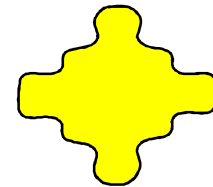


Training (73.15)

⌘ Other important aspects of 73.15:

- ☑ Entity must ensure that each individual received and understood training.
- ☑ Entity must record ID of individual, date of training, and means used to verify the employee understood the training.

Training (73.15)

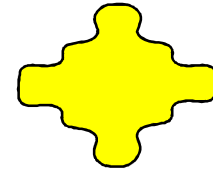


⌘ Why is training so critical?

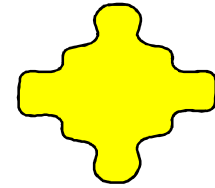
☒ This is a catchall: Boston incident.

☒ It does not matter that you have the top professionals in the world working for you, or that they have extensive educations. The regulations require training.

Responsible Officials (ROs) (73.9)



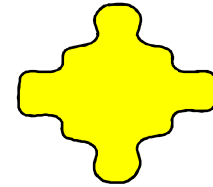
- ⌘ Must be “familiar” with Select Agent Program requirements.
- ⌘ Must have “authority and responsibility” to act on behalf of the entity.
- ⌘ The RO is responsible for ensuring compliance with the regulations, including:
 - ☒ Developing and implementing safety, security, and emergency response plans.
 - ☒ Allowing only approved individuals to have **access** to select agents and toxins.
 - ☒ Providing appropriate **training** for safety, security, and emergency response.
 - ☒ Properly **transferring** select agents or toxins.
 - ☒ Providing timely **notice of any theft, loss, or release**.
 - ☒ Maintaining detailed records.



RO Issues

- ⌘ ROs must have responsibility for acting on behalf of entity. So, probably not a good idea to delegate compliance to a consultant and take a hands off approach. **Precaution:** ROs work closely with your consultants.
- ⌘ ROs must be “familiar” with the regulations. **Precaution:** ROs should attend training sessions on the regulations and take time to become familiar with the regulations.

RO Issues



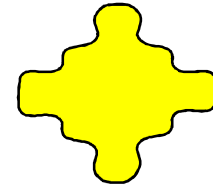
⌘ Is an RO personally liable for violations committed by their employer?

☒ Reg. does not state ROs are personally liable for violations. It states that they are responsible for ensuring compliance. But, Reg. does not give ROs immunity from penalties.

☒ Reg. drafted in this manner so that RO does not delegate compliance efforts to lower ranking employees?

☒ **Legal Issue**: At this point in the program, it is anybody's guess whether an RO could be held personally liable. The answer will probably depend on: 1) policy decision by CDC and OIG, 2) case by case determination depending on ROs bad conduct, and/or 3) technical legal analyses by OIG.

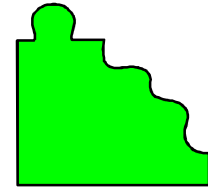
RO Issues



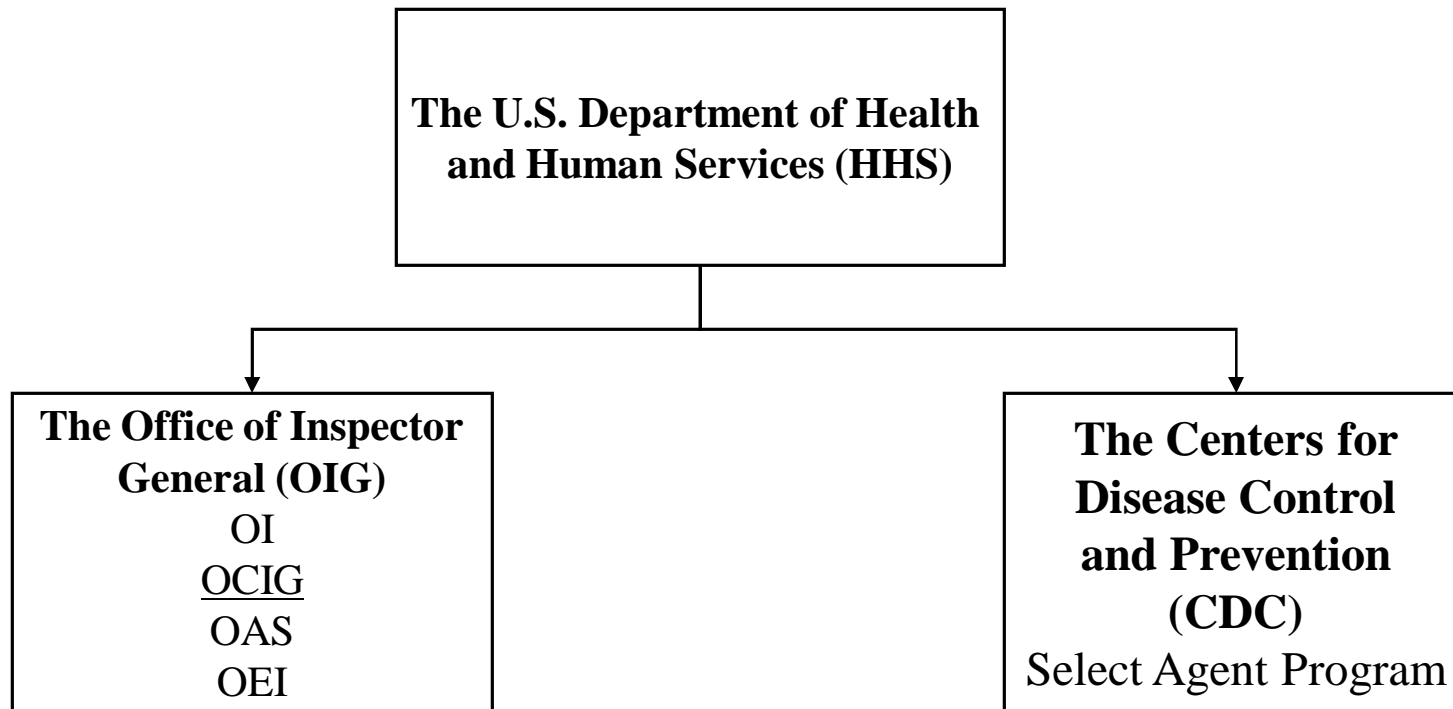
⌘ Dissolution of a Corporation? ROs (and officers) beware!

- ☒ **Orchestrate** proper destruction or transfer of agents or toxins.
- ☒ **Document** all information on destruction or transfer pursuant to Section 73.17 (Records).
- ☒ **Save** all records required by the program.
- ☒ **Check** with state and local authorities.

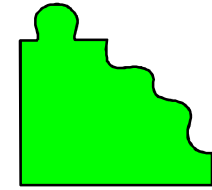
Primer on Select Agent Enforcement/ HHS



⌘ Organization within HHS.



Enforcement/ HHS



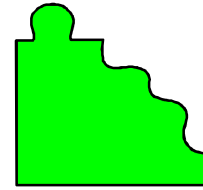
⌘ HHS investigations.

- ☒ Inspections being conducted by CDC employees and contractors.
- ☒ OIG/OAS or OEI may be conducting audits of companies similar to prior audits.
- ☒ “HHS” may without prior notification inspect any site, and inspect and copy any records. But, CDC usually provides notice of inspections.

⌘ The Office of Inspector General.

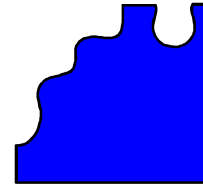
- ☒ Normally associated with Medicare and Medicaid fraud.
- ☒ Million dollar settlements with Pfizer, Schering Plough, and AstraZeneca.
- ☒ March 2003, the OIG was vested with enforcing “Civil Money Penalties” (CMPs) against violators of the Select Agent Program.

Anatomy of an enforcement action within HHS



- ⌘ CDC sends case to OIG for investigation.
- ⌘ OCIG may investigate (with or without OI), or send a “pre-demand letter.”
- ⌘ Pre-demand letter outlines the alleged violation and provides the entity an opportunity to explain the situation and offer a settlement to close the case.
- ⌘ After OCIG receives the response to the pre-demand, OCIG reviews and decides whether to close case or pursue case and CMP.
- ⌘ OCIG can subpoena documents and “depose” witnesses.
- ⌘ OCIG will either settle the case, or issue a “demand letter.” The demand letter signals the beginning of an administrative action against an entity.

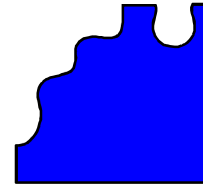
Holistic Compliance/ Seeing the forest through the trees



⌘ Remember your audience when it comes to CMPs/ The OIG focuses on five factors when assessing a penalty.

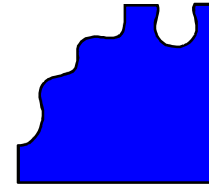
- ☒ Basically: How will the government perceive you?
 - ☒ Did you use your best efforts to comply or did you scoff at the regulations?
 - ☒ Organize your records and train your employees.
 - ☒ Calculate and document the amount of money and employee hours spent on compliance.
 - ☒ If possible, make compliance part of your corporate culture.
 - ☒ Don't be a recidivist.
 - ☒ Did you get high marks from a CDC inspection? Save the results. And, be skeptical.
 - ☒ Document your contributions to public health.

Holistic Compliance



- ⌘ All e-mails, letters, notes, etc. are “discoverable” in an investigation.
 - ☒ As part of your training, instruct employees to be professional. (No joking matter, don’t “belly ache” about compliance, don’t call CDC employees nasty names).
- ⌘ If it looks as though there will be an investigation, contact Goldberg Legal Services.
 - ☒ E-mails, letters, notes, memos, etc. cannot be protected unless they are privileged under the “attorney client privilege.”
 - ☒ Don’t transform yourself into Martha Stewart (i.e. destroy documents or lie).
- ⌘ Check into your state and local compliance obligations.
- ⌘ Expect the unexpected and diffuse situations before they become a problem.
 - ☒ Plan on the termination and possible disgruntlement of employees.

Holistic Compliance



⌘ High profile industry.

☒ Congressional interest:

- ☒ Senator Lieberman's November 12, 2003 letter and press release on timeliness of SRAs.
- ☒ House Select Committee on Homeland Security report dated October 25, 2004 on shortages of vaccines.

☒ Media interest:

- ☒ Anthrax, Ricin, SRI, Boston, and Thomas Butler incidents.
- ☒ ** Employees should not speak to the media.**

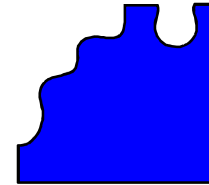
⌘ The regulations are a floor, not a ceiling.

- ☒ For instance: Train every six months instead of every year.

⌘ Share cost effective compliance ideas.

⌘ This area of law is still in its infancy.

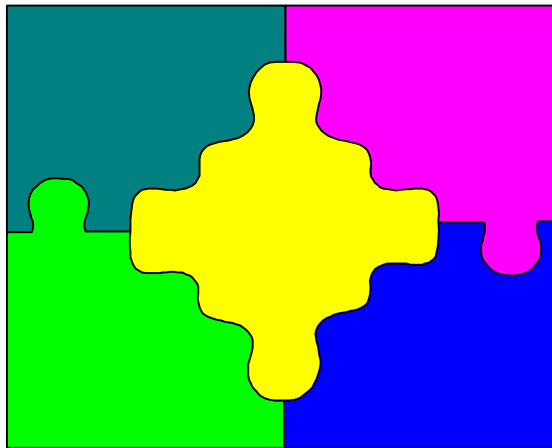
Predicting the future



⌘ Where do we go from here?

- ⏏ Precedents will be set by violations of law and incidents.
- ⏏ Enforcement will surely change based on administration.
- ⏏ CDC Select Agent Program will evolve:
 - ⏏ Inspection checklists.
 - ⏏ Standard training program for all inspectors.
 - ⏏ More inspectors, more inspections.
 - ⏏ Web based registration and forms.

Goldberg Legal Services/ The Complete Picture on Select Agent Law



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