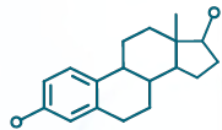


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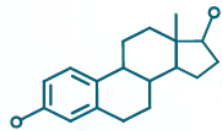
## Pharmaceutical Summit 2024



Welcome to the 3<sup>rd</sup> Annual Puerto Rico  
Pharmaceutical Summit 2024!

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## Pharmaceutical Summit 2024

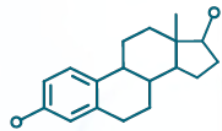


Remarks from  
Congresswoman Jennifer González



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## Pharmaceutical Summit 2024



Remarks from  
U.S. Senator Rick Scott





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## Pharmaceutical Summit 2024



### Somewhere Beyond the Sea: Experiences and Challenges of State Licensing and Distribution

#### PANELISTS:

- **Frank Fazio**, Principal, Porzio, Bromberg & Newman and Senior Vice President, Distribution and Licensing Services, Porzio Compliance Services
- **Jose Hernandez-Perez**, Project Manager, Novartis Pharmaceuticals Corp.
- **Margarita Marti-Lopez**, Compliance Manager, McNeil Healthcare LLC, Las Piedras, PR

# State Licensing

**State licenses are required for the distribution of drugs and devices.**

Licenses are required for the wholesale distribution of:

- Prescription drugs;
- Prescription devices;
- Over-the-counter drugs.

**States often have different license types and applications for different business models. Other states have just one license and all types of companies get the same license.**

The different categories of licenses are generally:

- Manufacturer or virtual manufacturer;
- Wholesaler or virtual wholesaler; and
- Third-party Logistics Provider (3PL).

# What Triggers a Requirement for Licensure

## **Distribution:**

Distribution can include both the transfer of possession as well as the transfer of title.

## **Stream of Commerce:**

Some states require a license if the product is available in the state without regard to who ships or sells it. This generally includes contract manufacturers.

## **Sales Representative Activity:**

The simple presence of sales representatives can trigger licensure requirements.

# Other Considerations

The type of product distributed or manufactured can impact the necessary licensure.

- ❖ Prescription drugs
- ❖ Controlled substances
- ❖ OTC Products
- ❖ Medical Devices



# Puerto Rico

Panel discussion regarding manufacturing and licensing in Puerto Rico.



# PORZIO

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## Bromberg & Newman



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## Bromberg & Newman



Margarita Marti-Lopez

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# PORZIO

## Pharmaceutical Summit 2024

### Conducting Internal Investigations: Best Practices to Address Compliance Concerns, Reduce Risk, and Access Results

PANELISTS:

- **Michelle D. Axelrod**, Principal, Porzio, Bromberg & Newman, P.C.
- **Jennifer A. Romanski**, Principal, Porzio, Bromberg & Newman, P.C.

# From the Headlines

## Manufacturing Lapses Found at Eli Lilly

**Failure to maintain equipment and facilities:** A recent FDA inspection of an Eli Lilly facility in NJ found several manufacturing violations including inadequate protections of electronic tracking records, failure to implement quality controls, neglect of equipment and facilities, and failure to properly train employees.

## Pharmasol Corporation Allegedly Adulterated its Drugs

**Failure to address defects and failure to clean and maintain equipment:** After multiple inspections and warnings by the FDA, Pharmasol Corporation was found guilty of manufacturing and distributing adulterated drugs when it failed to notify its customers about defects in its finished products, failed to establish a complaint procedure or corrective action plan, despite receiving 533 customer complaints relating to defects in its drug products, and failing to adequately clean and maintain its equipment.

**Ordered to recall:** The company agreed to recall all adulterated drugs, amongst other requirements.

## Morton Grove Allegedly Adulterated its Drugs

**Failure to implement adequate procedures and failure to investigate:** After several inspections by the FDA spanning the course of several years, and in a series of repeat violations, Morton Grove's manufacturing facility was found to have violated certain good manufacturing practices when it failed to have adequate procedures to prevent cross-contamination of equipment, failed to reject drug lots using a contaminated ingredient, and failed to fully investigate the root cause of the contamination.

**Ordered to destroy product:** The company agreed, amongst other requirements, to destroy all non-medically necessary drugs in the facility.

# From the Headlines

## Manufacturing Lapses Found at Novo Nordisk

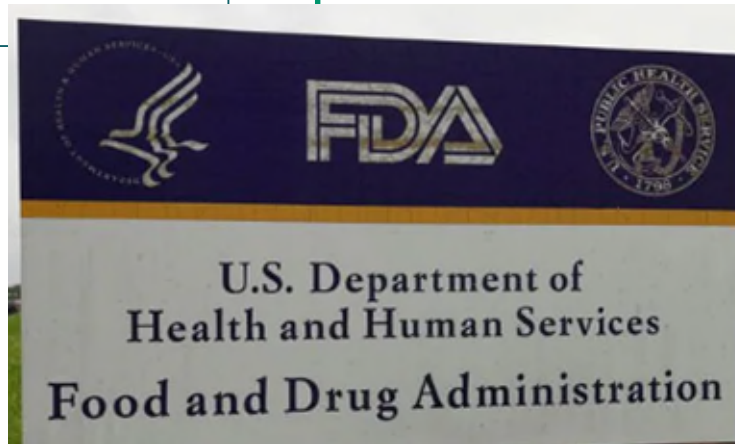
Failure to maintain facilities and equipment: Objectionable bacteria discovered in Novo's diabetes pill, leading to corrective actions by the company to mitigate harm and risks to the public.

## Sterilization Issues Found at Global Pharma Healthcare facility

Failure to ensure product sterility: After an inspection of a facility in India, the company recalled its eye drops due to their possible contamination and link to serious bacterial infections and death.

## Sale of Defective Medical Devices

Failure to timely disclose complaints: Philips Respironics sold defective CPAP machines before discovering contamination but failed to timely disclose complaints to the FDA.



## Eli Lilly Allegedly Altered Documents

Multiple individuals at the company allegedly re-wrote reports related to findings from research to show more favorable results regarding quality control at the facility.



# From the Headlines

## Puerto Rican Pharmaceutical Distributor Found Guilty of Failure to Make Reports

Failure to make reports and recordkeeping violations: Drogueria Betances, a distributor of pharmaceutical drugs, allegedly failed to report hundreds of “suspicious orders” for drugs (such as fentanyl and oxycodone) distributed to the company’s customers, including orders that were of unusual frequency, size, etc.

## TAPI Puerto Rico Ordered to Pay for Environmental Violations

Failure to comply with environmental regulations: After an inspection by the EPA, several areas of the facility's operations were found to be in violation of environmental regulations, including a failure to maintain facilities in a safe manner, failure to obtain a permit for waste storage and disposal, and failure to submit required annual toxic chemical release inventory reporting to the EPA.



# Why Do We Investigate?

- Addressing Complaints/Compliance Concerns Raised
- Regulatory/Legal Obligations
- Violations of SOPs/Procedures
- Patient Safety
- Process Considerations
- Quality Issues/Deviations

# DOJ: Properly Scoped Investigations by Qualified Personnel

- How does the company determine which complaints or red flags merit further investigation?
- How does the company ensure that investigations are properly scoped?
- What steps does the company take to ensure investigations are independent, objective, appropriately conducted, and properly documented?
- How does the company determine who should conduct an investigation, and who makes that determination?

US DOJ Criminal Division, *Evaluation of Corporate Compliance Programs*, Updated March 2023



# Before the Investigation...

- Do you have an investigation policy/protocol/plan?
- Consider the scope of the investigation and how the incident was raised
- Consider what is known versus unknown
- Determine who should conduct the investigation
  - Determine whether legal counsel should be involved
  - Internal vs. external investigator?
  - Need for escalation/senior management involvement?
  - Avoid conflicts of interest and maintain privilege
- Consider whether any notice of the issue raised must be made to company leadership, regulatory authorities, other third parties (e.g., contractual obligations)

# Preparing For an Internal Investigation

- Assess risk level
  - Policy v. non-policy issue
  - Patient safety
  - Employee safety
  
- Document & data preservation
  - Notification of document hold/preservation of documents
  - Engage IT and other key stakeholder support early in process
  
- Investigation plan
  - Witness list – identify a logical sequence
  - Documents to be retrieved
  - Key questions to be answered



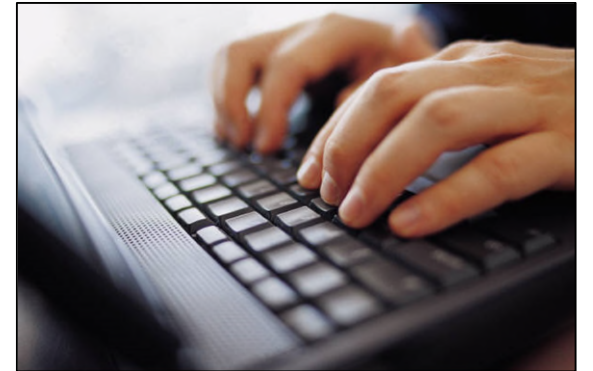
# Investigation Process/Plan

- Develop a plan for the investigation. This will guide the investigation and help keep things on track
  - Document collection and review
  - Interviews
  - Timing
  - Use of in-house or outside counsel (potential assertion of attorney-client privilege)
  - Reports to Company leadership/Compliance
  - Corrective and preventative action
  - Discipline
  - Notification requirements to outside parties
  - Documentation of changes/upgrades
  - Monitoring of implementation of changes/upgrades



# Document Collection and Review

- Identify relevant policies, procedures & methods
- Identify relevant people, facility, equipment, etc.
- Collect & review documents
  - Ask for notes if available
  - Obtain copies of relevant reports, analyses
- Access electronic evidence
  - Imaging of computers or other resources (e.g., databases)
  - Local data protection laws
  - Custodians – start with witnesses & keywords
- Remind witnesses to retain relevant documents (consider document holds)
- Seek corroborating evidence as needed
- Consider prior investigations/review historical data



# Interviewing

- Consider who should be interviewed
  - Individual making report or complaint, involved parties, witnesses, authors of relevant documents, others identified as having relevant information
- Establish the right sequence of interviewees...BUT what is the right sequence?
  - If complaint, interview complainant first
- Prepare an outline or discussion guide... but be prepared to go off script
- Decide which approach makes sense, phone vs. face-to-face/video
- Bring at least two interviewers (lead and secondary) – one to ask questions, one to take notes
- Avoid back-to-back interviews (if possible), inappropriate interview settings, jumping to conclusions, suggesting an outcome, making promises about how information obtained will be used



# Interviewing

- Key points to increase the probability of success
  - Opening statements for interviews
    - May vary, depending on the nature of the investigation
    - Distinction between Company as client vs Employee as client
      - Upjohn Warning/Notice of Representation
    - Company may waive privilege and disclose information
  - Be serious, but non-confrontational
  - Avoid leading questions
  - Rely on open-ended questions especially early in the investigations
  - Stay aware of the time
  - Prepare an interview memo as soon as possible
    - At least read and correct notes immediately





# Investigation Process/Plan

## ➤ Common pitfalls to avoid:

- Bias
- Conflicts of interest
- Use of more than one investigator/interviewer
- Lack of fairness
- Making Assumptions/Rushing to Judgement
  - Near the end of the investigation, examine the facts *as if you've drawn the completely wrong conclusion*; see if the alternative holds water
  - Especially relevant in complex situations



# Investigation Process/Plan

## ➤ Common pitfalls to avoid, cont.:

- Failure to get to the root of the problem
- Distraction/lack of focus
- Neglecting to bring outside consultants within scope of privilege
- Offering assurances as to how evidence will be used
- Forgetting to remind everyone who comes in contact with the work to maintain confidentiality
- Taking on too much
  - Other workload
  - More than one investigation simultaneously



# Assessing the Information

- Key points to increase the probability of success
  - Go back to some interviewees if needed
  - Assess the credibility of witnesses
    - Motive, Demeanor, Recollection, Prior Statements, Cooperation
  - Catalog/Categorize information on a spreadsheet; sorting can be extremely helpful later in the investigation
  - Carefully consider whether the parties were actually trained properly
    - Check-the-box training may not be reasonable
  - Determine if the company has a true open door/non-retaliation environment





# Assessing the Information

## ➤ Key common pitfalls to avoid

- Fatigue
- Bias
- Following every “rabbit hole”
- Failure to consider systemic issues
  - Inadequate internal controls
  - Insufficient training/communication about policies
  - Fear of retaliation



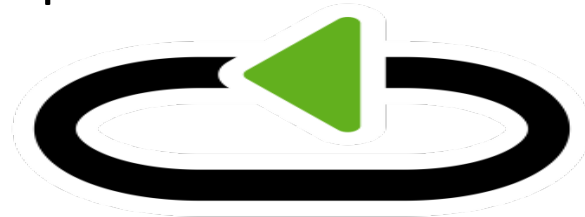
# DOJ: Investigation Response

- Does the company apply timing metrics to ensure responsiveness?
- Does the company have a process for monitoring the outcome of investigations and ensuring accountability for the response to any findings or recommendations?

US DOJ Criminal Division, **Evaluation of Corporate Compliance Programs**, Updated March 2023

# Conclusion/Corrective Action

- Key points to increase the probability of success
  - Prepare investigation report or summary
  - Consult with HR, Labor & Employment counsel, other stakeholders prior to taking corrective action
  - Consider whether witnesses &/or complainant are at risk of potential retaliation
  - Consider other remediation/preventative actions
  - Close the loop with complainant





# Conclusion/Corrective Action

- Common pitfalls to avoid
  - Taking too long to close out
  - Taking corrective action that is too broad



# DOJ: Resources and Tracking of Results

- Are the reporting and investigating mechanisms sufficiently funded?
- How has the company collected, tracked, analyzed, and used information from its reporting mechanisms?
- Does the company periodically analyze the reports or investigation findings for patterns of misconduct or other red flags for compliance weaknesses?

US DOJ Criminal Division, **Evaluation of Corporate Compliance Programs**, Updated March 2023

# Special Case - OUS

- Considerations when reported incident occurred outside of the United States
  - Consult with local counsel early on
  - Consider local investigators
  - Remember privacy



# PORZIO



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# PORZIO

## Pharmaceutical Summit 2024

### DOJ Investigations, Product Adulterations, and Class Actions: Dealing with a Corporate Emergency

#### PANELISTS:

- Vito A. Gagliardi, Jr., Managing Principal, Porzio, Bromberg & Newman, P.C.
- Karen Garnik, APR, Founder, Global Vision Communications
- William J. Hughes, Jr., Principal, Porzio, Bromberg & Newman, P.C.
- Raquel R. Rivera, Counsel, Porzio, Bromberg & Newman, P.C.
- Nick Uehlecke, Principal, Todd Strategy Group

# When is a Situation an Emergency?

Grand Jury Subpoena

United States District Court  
SOUTHERN DISTRICT OF NEW YORK

TO: Law Enforcement National Security  
Microsoft Corporation, USA  
1 Microsoft Way  
Redmond, WA 98052

GREETINGS:

WE COMMAND YOU that all and singular business and excuses being laid aside, you appear and attend before the GRAND JURY of the people of the United States for the Southern District of New York, at the United States Courthouse, 40 Foley Square, Room 220, in the Borough of Manhattan, City of New York, New York, in the Southern District of New York, at the following date, time and place:

Appearance Date: November 30, 2020 Appearance Time: 10:00 a.m.

to testify and give evidence in regard to an alleged violation of:

18 U.S.C. §§ 371, 873, 1952, 2314, 2315, 2261A

and not to depart the Grand Jury without leave thereof, or of the United States Attorney, and that you bring with you and produce at the above time and place the following:

See Attached Rider

N.B.: Personal appearance is not required if the requested documents are: (1) produced on or before the return date to Special Agent John Vouderis, Federal Bureau of Investigation, [REDACTED], New York, New York 10278, [REDACTED]@fbi.gov, [REDACTED]; and (2) accompanied by an executed copy of the attached

Failure to attend and produce any items hereby demanded will constitute contempt of court and will subject you to civil sanctions and criminal penalties, in addition to other penalties of the Law.

DATED: New York, New York  
November 22, 2020

*Audrey Strauss/RBS*  
AUDREY STRAUSS  
Acting United States Attorney for the  
Southern District of New York

*Robert B. Sobelman*  
Robert B. Sobelman  
Assistant United States Attorney

[REDACTED]  
New York, New York 10007  
Telephone: [REDACTED]





# When is a Situation an Emergency?

- Qui Tam Complaint
  - Civil Investigation
  - Criminal Investigation
- Product Malfunction/Adulteration
  - Regulatory Agency Action
  - Class Action/Mass Tort
  - Congressional Hearings
- Social Media/Bad Press
  - Ex-Employee Complaints
  - Customer Complaints

# Government Investigations

Grand Jury Subpoena

United States District Court  
SOUTHERN DISTRICT OF NEW YORK

TO: Law Enforcement National Security  
Microsoft Corporation, USA  
1 Microsoft Way  
Redmond, WA 98052

GREETINGS:

WE COMMAND YOU that all and singular business and excuses being laid aside, you appear and attend before the GRAND JURY of the people of the United States for the Southern District of New York, at the United States Courthouse, 40 Foley Square, Room 220, in the Borough of Manhattan, City of New York, New York, in the Southern District of New York, at the following date, time and place:

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*Sobelman*  






# Government Investigations

Miami Luken  
Congressional Testimony



# Product Malfunction/Adulteration

1982 Tylenol  
Adulteration  
Chicago, IL





# Social Media/Bad Press

Kyte Baby CEO Ying LIU  
Apology #1



# Social Media/Bad Press

Kyte Baby CEO Ying LIU  
Apology #2



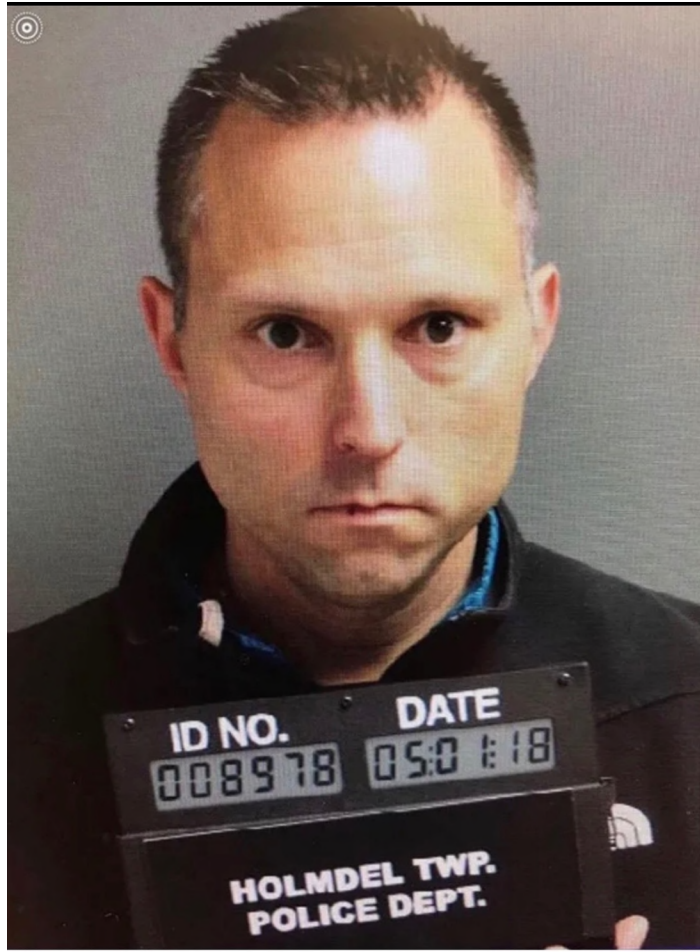


# Social Media/Bad Press

Dave Carroll  
“United Breaks Guitars,  
Song 2”



# Dr. Thomas Tramaglino



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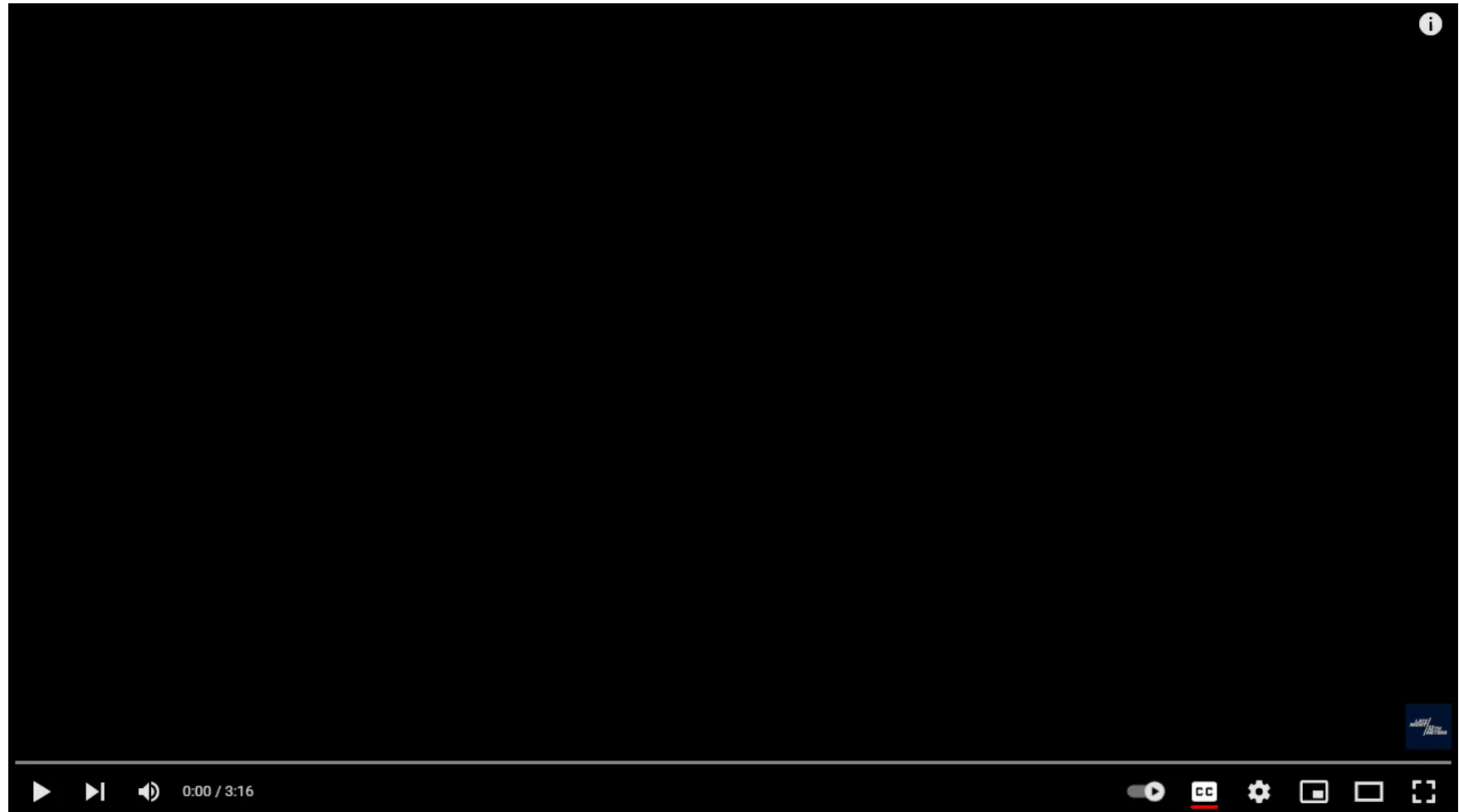
# fax

TO: President Nancy Zimmerman FROM: Community of Kenilworth, NJ  
FAX: 908 709 7315 PAGES: 3  
PHONE: Dr. Thomas Tramaglino DATE: Arrest Date May 1st 2018  
RE: Defecating on SCHOOLS Grounds

Urgent  For Review  Please Comment  Please Reply  Please Recycle

What you going to do about this, you can contact Holmdel Police Department to get the real story, but my tax Dollars will not pay for a man like this to be a part of our school system.

# Dr. Thomas Tramaglino





# PORZIO

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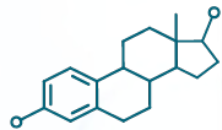
Principal

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# PORZIO

## Pharmaceutical Summit 2024



Thank You for Joining Us!