

From: Sarah Ryan Dodge [REDACTED]  
Sent: Thursday, February 05, 2009 7:31 AM  
To: Dana Reed-Kane  
Subject: FW: FDA Inspections - Constitutionality Issues Search & Seizure  
Importance: High

Dana,

Here is some starting materials for Matt Slimp (including the existing issue paper from IACP) and some past court cases on FDA inspection cases. The overall goal of the seminar would be to focus on the balancing of what you need to do when the FDA comes knocking on your door to be compliant and what you DON'T need to do (and shouldn't do) to protect your Constitutional rights.

Given what has happened with some pharmacists signing away their rights through these affidavits, etc. I want to have some really strong messaging inserted into the presentation about the need to consult one's attorney and when a pharmacist should NOT provide certain information to the FDA. Also, Matt should especially note likely situations when the FDA is overstepping its bounds and when pharmacists should draw the line and discontinue the visit and call their attorney. We need to provide as much information as we can to prevent pharmacists from potentially self-incriminating or giving the FDA information that could put pharmacists in a position to be sued by patients or others.

Sarah

