

R E C E I V E D
MAR 26 2013

STATE OF MICHIGAN
IN THE COURT OF APPEALS

COURT OF APPEALS
FOURTH DISTRICT
LARRY S. ROYSTER
CHIEF CLERK

***In Re* PETITION OF THE ATTORNEY
GENERAL**

Court of Appeals No. _____

_____ /

PETITION FOR MULTI-COUNTY GRAND JURY

BILL SCHUETTE, Attorney General of the State of Michigan, petitions this Honorable Court, pursuant to MCL 767.7b(1) and MCR 7.203(C), for a multi-county grand jury, saying:

NATURE OF THE REQUEST

1. MCL 767.7b(1) authorizes this Court to convene a grand jury with jurisdiction over two or more counties in this state in response to a petition of the attorney general.
2. Attorney General Bill Schuette respectfully requests the convening of a grand jury with jurisdiction over the Counties of Genesee, Grand Traverse, Livingston, and Macomb. There is probable cause to believe that crimes have been committed in these counties based on coordinated action that violates MCL 333.17764, which makes it a crime for a person to knowingly or recklessly sell, offer for sale, possess for sale, cause to be sold, or manufacture for sale an adulterated drug.

STATEMENT SETTING FORTH PROBABLE CAUSE

3. The following facts, all of which are in the public record, demonstrate probable cause that a crime has been committed in violation of MCL 333.17764.

4. The Centers for Disease Control and Prevention (CDC), a part of the United States Department of Health and Human Services, is the primary federal agency for conducting and supporting public health activities in this country. On September 21, 2012, the Tennessee Department of Health notified the CDC of a patient with the onset of meningitis approximately 19 days following an epidural steroid injection at a Tennessee ambulatory surgery center. The injected substance had been prepared by New England Compounding Center (NECC), at its facility in Framingham, Massachusetts.

5. On September 25, 2012, NECC voluntarily recalled certain lots of injectable methylprednisolone acetate (PF) 80mg/ml, the substance linked to the meningitis case. On October 3, 2012, NECC ceased all production and initiated recall of all methylprednisolone acetate and other drug products prepared for intrathecal administration.

6. On October 4, 2012, the CDC issued an Official Health Advisory. This advisory informed the public that the CDC and the Food and Drug Administration (FDA) were coordinating a multi-state investigation of fungal meningitis among patients who received an epidural steroid injection. The CDC reported that as of that date a total of 35 cases in six states had been identified with a clinical picture

consistent with fungal infection. All 35 cases were linked to medications prepared by NECC.

7. In an Official Health Advisory dated October 8, 2012, the CDC reported that the FDA had observed "fungal contamination by direct microscopic examination of foreign matter taken from a sealed vial of methylprednisolone acetate collected from the New England Compounding Center." The advisory further noted that the reported cases had substantially increased in just four days. The CDC then reported the tally had grown to 105 cases, including eight deaths, in nine different states. These numbers include 21 cases, with two deaths, in Michigan.

8. The CDC has continued to receive new reports of fungal infection among patients who were given injections of contaminated methylprednisolone acetate prepared by NECC, and has continued to issue periodic official health advisories concerning their investigation. In an advisory dated March 4, 2013, the CDC advised that a total of 720 cases, which includes 48 deaths, have been reported in 20 states. This number includes 255 cases, with 14 deaths, in Michigan. The CDC advisory reports establish that our State is the epicenter of the meningitis outbreak.

9. During its investigation, the CDC determined that the suspect lots of steroid medication were sold by NECC to various customers throughout the country. The agency identified four separate facilities in Michigan that received the probably adulterated lots of the substance. The names and locations of those facilities are: Michigan Pain Specialists in Brighton (Livingston County);

Neuromuscular Institute in Grand Blanc (Genesee County); Neuromuscular and Rehabilitation in Traverse City (Grand Traverse County); and Southeast Michigan Surgical Hospital in Warren (Macomb County). These are the four counties covered by this grand-jury request.

10. The Michigan Department of Community Health has publicly disclosed non-identifying information as to each of the 14 Michigan deaths:

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|-------------------------|-------------------|--------------------|
| • Grand Traverse County | 80 year old man | Confirmed 3/11/13 |
| • Grand Traverse County | 73 year old man | Confirmed 2/6/13 |
| • Washtenaw County | 88 year old woman | Confirmed 1/14/13 |
| • Washtenaw County | 87 year old woman | Confirmed 1/3/13 |
| • Livingston County | 75 year old woman | Confirmed 11/20/12 |
| • Livingston County | 50 year old woman | Confirmed 11/19/12 |
| • Ingham County | 88 year old woman | Confirmed 11/7/12 |
| • Charlevoix County | 81 year old woman | Confirmed 10/30/12 |
| • Wayne County | 64 year old woman | Confirmed 10/30/12 |
| • Livingston County | 79 year old woman | Confirmed 10/18/12 |
| • Washtenaw County | 61 year old man | Confirmed 10/17/12 |
| • Livingston County | 67 year old woman | Confirmed 10/6/12 |
| • Genesee County | 56 year old woman | Confirmed 10/9/12 |
| • Washtenaw County | 78 year old woman | Confirmed 10/6/12 |

11. Pharmaceutical compounding is the creation of a particular pharmaceutical product to fit the unique needs of a specific, individual patient. To do this, compounding pharmacists combine or process appropriate ingredients. This may be done for medically necessary reasons, such as to change the form of the medication from a solid pill to a liquid, to avoid a non-essential ingredient that the patient is allergic to, or to obtain the exact dose needed of particular active ingredients. It may also be done for more optional reasons, such as adding flavors to a medication or otherwise altering taste or texture.

12. Compounding differs from drug manufacturing. Compounding occurs when a given drug product is made or modified to have characteristics that are specifically contemplated for an individual patient. Compounders must have a separate prescription for each individual patient. Pharmaceutical manufacturing, in contrast, is the preparation of drug products for the mass market. Manufacturers need not have a separate prescription for an individual patient.

13. Pharmaceutical manufacturing is regulated by the FDA, while pharmaceutical compounding is not. Instead, drug compounding is regulated by the individual states. At the time NECC shipped the suspected lots of medication to the Michigan facilities, it was licensed as a pharmaceutical compounder in both Massachusetts and Michigan. It was not licensed as a drug manufacturer in either state.

14. *60 Minutes* is a television news magazine produced by CBS News. It has won more Emmy Awards than any other primetime broadcast, including a special Lifetime Achievement Emmy. It has also won every major broadcast journalism award over its tenure, including 18 Peabody and 14 DuPont Columbia University awards for excellence in television broadcasting. Other distinguished awards won multiple times include the George Polk, RTNDA Edward R. Murrow, Investigative Reporters and Editors, RPK Journalism, Sigma Delta Chi and Gerald Loeb Awards for Distinguished Business and Financial Reporting. *60 Minutes*, the most successful television broadcast in history, began its 45th season in September 2012.

15. On March 10, 2013, *60 Minutes* aired a segment entitled "Lethal Medicine." In that segment, correspondent Scott Pelley reported that 17,000 vials of a contaminated steroid produced by NECC were shipped to clinics and hospitals in 23 states last fall. During the segment, Pelley interviewed a person identified as a technician at the NECC lab which produced the steroids. That person was identified as Joe Connolly.

16. Joe Connolly reported that in 2011 NECC went from being a true compounder to an actual drug manufacturer. He stated that the lab was overwhelmed with orders, and output of the drugs he made increased by a factor of 1,000. He indicated that NECC wanted to manufacture the drugs without being subject to the oversight required of a manufacturer.

17. Joe Connolly further reported that as a result of the increased production the lab got overtaxed and technicians found it difficult to follow the strict procedures that kept drug production sterile. He stated that the technicians would occasionally find mold in the clean room where the drugs were produced. He was told to simply clean it up, and continue the process to produce the drugs.

18. Connolly stated during the interview that he warned his supervisor about the inherent dangers of the process they were using to produce the drugs. He noted to his supervisor that they had moved from compounding to manufacturing. Connolly stated that he told the supervisor that the way things were going something was going to get missed and a patient was going to get hurt. Connolly

reported that the supervisor just shrugged. He said that was the standard response to stated concerns about the matter.

19. Scott Pelley also interviewed another person who was represented to be a former salesman with NECC. That person's name was not given, and he was disguised during the interview. Pelley reported that this was done because the salesman fears the connection with NECC will ruin his career.

20. Pelley reported that the salesman left NECC a year before the steroid disaster and was replaced by a competing salesperson. Pelley further reported that the salesman told him that many of NECC's clients were in on a fraud at the heart of the company's growth. Such fraud arose from the fact that the laws concerning compounding required NECC to have a name for each prescription. In many instances, the customer simply made up a name.

21. During the segment, the salesman reported that customer-clinics sometimes gave obvious fraudulent names like Bart Simpson and Homer Simpson. In such instances the salespersons would get back to them, only to receive follow-up names like John Doe, Jane Doe, Jane Smith and Bill Smith. The salespersons would tell them to at least give legitimate names, even though there were no identified customers. He stated that sometimes the customers would use an office phone directory, and simply scribble out the person's extension number and fax it to NECC. It was obvious to the salesman that the customer-clinics were not acting above board. However, he did not identify any of the customer-clinics during the interview.

22. The salesman stated that there was a strong profit motive for the customers to engage in such activity. Because NECC was not being regulated by the FDA in the manner that a manufacturer should have been, it could provide the drugs at a far lower cost. But he was often told by legitimate clinics that they would not do business with NECC because the company was not doing things right. When that occurred, the sales staff simply moved on to the next potential customer.

23. At the conclusion of the segment, Scott Pelley reported that NECC has gone into bankruptcy. He further reported that the principal owners of the company withdrew \$16 million from the company over the last year, some of it as people were beginning to die.

24. Under Michigan law, it is a crime for a person to knowingly or recklessly sell, offer for sale, possess for sale, cause to be sold, or manufacture for sale an adulterated drug. The seriousness of the crime, and the possible penalty, depends upon the harm inflicted on the person receiving the adulterated drug. When a serious impairment of bodily function results, the crime is a five-year felony. When a death results, the crime is a 15-year felony. MCL 333.17764.

25. There is probable cause to believe that NECC sent adulterated drugs to one or more Michigan counties and that NECC knew or had reason to know that the adulterated drugs could cause great bodily harm or death.

26. Further, under Michigan law, it is a crime for a person to conspire with another to do a lawful act in an unlawful manner. This type of conspiracy is a five-year felony. MCL 750.157a.

REASONS TO CONVENE A GRAND JURY

27. As demonstrated by the fact that the salesman saw a need to be disguised during his interview, there are likely to be many persons, whose names are not presently known, who have knowledge about the meningitis outbreak, and who are able to give material evidence concerning the matter, but are unwilling to give evidence or information, except before an authorized court of justice, where their legal rights will be fully protected in any disclosures they may make about the matter.

28. Owing to the secrecy that has surrounded the actions of NECC management, the Michigan healthcare facilities where the steroid shots were injected, and the names and identities of the specific persons responsible for the matter, it is difficult for law enforcement officers to apprehend any suspects, and bring them to justice.

29. A grand jury can require the attendance before it of the witnesses who have knowledge of the matter and the names of the perpetrators, and require those persons to give testimony under oath. Accordingly, if this Honorable Court will convene a multi-county grand jury, under the provisions of statute, for the purpose of investigating this matter, sufficient information and evidence will be secured to enable law enforcement officials of this State to apprehend the persons guilty of criminal offenses and bring them before the proper court, so that they be dealt with as law and justice require.

RELIEF REQUESTED

There is probable cause to believe that a crime, or a portion of a crime, has been committed in two or more of the counties named in this petition, and there are valid reasons to convene a grand jury with jurisdiction over all the counties named in this petition. Accordingly, the Attorney General respectfully requests that the Court convene a multi-county grand jury under MCL 767.7b and MCR 7.203(C) and issue an order containing the designations required by MCL 767.7e.



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