Nationally distributed medications from compounding pharmacies, which typically adhere to less stringent quality-control standards than pharmaceutical manufacturers, can lead to multistate outbreaks. We investigated a cluster of 6 patients in a Maryland hospital who had *Sphingomonas paucimobilis* bloodstream infections in November 2007. Of the 6 case-patients, 5 (83%) had received intravenous fentanyl within 48 hours before bacteremia developed. Cultures of unopened samples of fentanyl grew *S. paucimobilis*; the pulsed-field gel electrophoresis pattern was indistinguishable from that of the isolates of 5 case-patients. The contaminated fentanyl lot had been prepared at a compounding pharmacy and distributed to 4 states. Subsequently, in California, *S. paucimobilis* bacteremia was diagnosed for 2 patients who had received intravenous fentanyl from the same compounding pharmacy. These pharmacies should adopt more stringent quality-control measures, including prerelease product testing, when compounding and distributing large quantities of sterile preparations.
Compounding pharmacies are licensed or registered by state pharmacy boards to combine “reasonable quantities” of ingredients to fill a valid prescription from a licensed practitioner for an individual patient (1). Some pharmacies, however, have moved beyond this role and, in anticipation of receiving routine orders, prepare larger quantities of compounded preparations for national distribution to healthcare facilities (2,3). Nationally distributed medications from compounding pharmacies, which typically adhere to less stringent quality-control standards than pharmaceutical manufacturers, can lead to multi-state outbreaks that may be difficult to detect. Sunenshine et al. recently reported a 5-state outbreak of *Serratia marcescens* bloodstream infections associated with contaminated intravenous magnesium sulfate from a compounding pharmacy (3). Other reported outbreaks caused by contaminated medications from compounding pharmacies include the following: *S. marcescens* infections associated with betamethasone injection, *Pseudomonas putida* septicemia caused by use of contaminated flush solutions in a special-care nursery, *Burkholderia cepacia* infections caused by contaminated intravenous flush solutions, *Pseudomonas fluorescens* bloodstream infections associated with a heparin/saline flush, and *Exophiala dermattitidis* infections caused by injection of contaminated steroids (4–10; Table 1).

*Sphingomonas paucimobilis* is an aerobic bacterium found in soil and water; it is a rare cause of healthcare-associated infections (11,12). *S. paucimobilis* has been reported to cause outbreaks of bacteremia among immunocompromised patients in hematology and oncology units; these outbreaks are possibly related to bacterial colonization of hospital water systems (13,14). An *S. paucimobilis* outbreak in mechanically ventilated neonates was linked to contaminated temperature probes (15). In November 2007, The Johns Hopkins Hospital Department of Hospital Epidemiology and Infection Control initiated an outbreak investigation after being notified by the hospital’s microbiology laboratory of the growth of *S. paucimobilis* in several patients’ blood cultures over a 2-week period.

### Methods

The Johns Hopkins Hospital is a 926-bed, tertiary-care, academic hospital in Baltimore, Maryland, USA. For this investigation, we defined a case-patient as any patient in our hospital whose cultures of blood or of other normally sterile body sites grew *S. paucimobilis* in November 2007. *S. paucimobilis* isolates were characterized as gram-negative rods that are yellow-pigmented, glucose nonfermenting, and weakly oxidase positive; they were preliminarily identified by the BD Phoenix Automated Microbiology System (BD Diagnostics, Inc. Sparks, MD, USA). All *S. paucimobilis* isolates were confirmed by cell wall fatty acid analysis using gas liquid chromatography (Sherlock Microbial Identification System version 4.5, library 5.0; MIDI, Inc. Newark, DE, USA). Microbiology records from January 2006 through November 2007 were examined to identify case-patients and to establish the baseline rate of *S. paucimobilis* bacteremia. We identified common exposures for case-patients and focused on intravenous infusions, medications, and contrast agents and on case-patients’ clinical signs, treatments, and outcomes. Because most of the blood cultures growing *S. paucimobilis* were collected in BacT/Alert FA bottles containing activated charcoal (bioMérieux, Durham, NC, USA), we cultured noninoculated bottles from clinical units by placing them directly into the blood culture instrument to assess for intrinsic contamination. On the basis of information from the medical record review, samples for bacterial culture were taken from 4 implicated lots of intravenous fentanyl mixed in 0.9% sodium chloride solution. All 4 lots came from an out-of-state compounding pharmacy.

### Table 1. Recently published reports of infectious outbreaks associated with contaminated medications prepared at compounding pharmacies, United States, 2002–2007

<table>
<thead>
<tr>
<th>Reference</th>
<th>Organism</th>
<th>Infection (no. patients)</th>
<th>Mode of transmission</th>
<th>Location of outbreak</th>
</tr>
</thead>
<tbody>
<tr>
<td>(3)</td>
<td><em>Serratia marcescens</em></td>
<td>Bloodstream infections (18)</td>
<td>Intravenous magnesium sulfate</td>
<td>California, New Jersey, New York, Massachusetts, California</td>
</tr>
<tr>
<td>(4)</td>
<td><em>S. marcescens</em></td>
<td>Meningitis, epidural abscess, or joint infection (11)*</td>
<td>Epidural or intra-articular injection of betamethasone</td>
<td>North Carolina, New York, Massachusetts, California</td>
</tr>
<tr>
<td>(6)</td>
<td><em>Burkholderia cepacia</em></td>
<td>Bloodstream infections and sepsis (2 pediatric patients)</td>
<td>Intravenous antibiotic-lock flush solution</td>
<td>Connecticut</td>
</tr>
<tr>
<td>(7)</td>
<td>Hepatitis C virus</td>
<td>Acute hepatitis C (16)</td>
<td>Injected radiopharmaceutical for myocardial perfusion study</td>
<td>3 clinics in Maryland</td>
</tr>
<tr>
<td>(8,10)</td>
<td><em>Pseudomonas fluorescens</em></td>
<td>Bloodstream infections (64)</td>
<td>Heparin/saline intravenous flush</td>
<td>Missouri, New York, Texas, Michigan, South Dakota</td>
</tr>
<tr>
<td>(9)</td>
<td><em>Exophiala dermatitidis</em></td>
<td>Meningitis (5)†</td>
<td>Epidural injection of methylprednisolone‡</td>
<td>2 pain management clinics in North Carolina</td>
</tr>
</tbody>
</table>

*3 case-patients died.
†1 case-patient died.
‡Prepared by a compounding pharmacy in South Carolina and supplied to hospitals and clinics in 5 states.
hereafter called pharmacy A. All *S. paucimobilis* isolates were strain typed by pulsed-field gel electrophoresis (PFGE) after digestion with *XbaI* using standard methods and interpreted according to criteria established by Tenover et al. (16).

We investigated the possibility that fentanyl had been tampered with or diverted by tracing the narcotic chain of custody, reviewing controlled substance procedures, visually inspecting fentanyl bags for signs of tampering, testing fentanyl concentrations, and analyzing personnel access records from the automated medication management system (Pyxis, Cardinal Health; www.cardinal.com/us/en/providers/products/pyxis/index.asp). The investigation was coordinated with public health authorities, including the Centers for Disease Control and Prevention (CDC) and the Baltimore City Health Department. CDC performed a multistate case-finding investigation by working with the compounding pharmacy to trace the distribution of implicated lots of intravenous fentanyl and by asking recipient healthcare institutions whether they had identified cases of *S. paucimobilis* bacteremia. We notified the US Food and Drug Administration (FDA) of our findings, and the FDA investigated compounding practices at pharmacy A. The Johns Hopkins University Institutional Review Board approved this study and waived informed consent.

## Results

*S. paucimobilis* was isolated from the blood cultures of 6 patients; the samples were collected from November 11 through November 23, 2007. The organism was not isolated from cultures of any other body site. Case-patients had various underlying medical conditions and had been admitted to different hospital units: neurologic intensive care unit (3 patients), medical intensive care unit (1 patient), oncology center (1 patient), and medicine unit (1 patient) (Table 2). *S. paucimobilis* grew in multiple sets of blood cultures (5 patients) and from blood cultures collected on >1 date (3 patients). In the preceding 22 months, *S. paucimobilis* had been isolated from blood cultures of 4 patients (Figure 1).

As a result of *S. paucimobilis* bloodstream infections, 5 of the case-patients reported here received antimicrobial drug treatment and had central intravenous catheters or implanted medication ports removed and replaced. One of these patients had an adverse reaction (rash and renal insufficiency) to antimicrobial drug treatment. All 5 patients treated with antimicrobial agents became free of *S. paucimobilis* bloodstream infection and survived. One patient (patient 5, Table 2) died of group A streptococcal sepsis before blood culture results for *S. paucimobilis* were available.

No breaches of infection control procedures or inappropriate blood culture practices were identified. Blood for culture was collected by staff in each unit rather than by

### Table 2. Demographic and clinical characteristics of patients with *Sphingomonas paucimobilis* bloodstream infection, United States, 2007

<table>
<thead>
<tr>
<th>Patient no./age, y/gender</th>
<th>Hospital unit (US state)</th>
<th>Clinical diagnosis</th>
<th>Date(s) of fentanyl administration†</th>
<th>Date(s) of infection</th>
<th>Treatment</th>
<th>Outcome</th>
<th>PFGE strain‡</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/65/M</td>
<td>Medicine (MD)</td>
<td>Osteomyelitis; MRSA wound infection</td>
<td>NA</td>
<td>Nov 14</td>
<td>ADT, central line removed and replaced</td>
<td>Survived</td>
<td>Unique</td>
</tr>
<tr>
<td>2/64/M</td>
<td>NCCU (MD)</td>
<td>Subarachnoid hemorrhage</td>
<td>Oct 29–31, Nov 2–3, Nov 11–22</td>
<td>Nov 14, Nov 18</td>
<td>ADT, central line removed and replaced</td>
<td>Survived</td>
<td>A</td>
</tr>
<tr>
<td>3/46/F</td>
<td>NCCU (MD)</td>
<td>Subarachnoid hemorrhage</td>
<td>Nov 10–11</td>
<td>Nov 11</td>
<td>ADT, central line removed and replaced</td>
<td>Survived</td>
<td>A</td>
</tr>
<tr>
<td>4/69/F</td>
<td>NCCU (MD)</td>
<td>Subarachnoid hemorrhage</td>
<td>Nov 18</td>
<td>Nov 18</td>
<td>ADT, central line removed and replaced</td>
<td>Survived</td>
<td>A</td>
</tr>
<tr>
<td>5/38/F</td>
<td>MICU (MD)</td>
<td>Group A streptococcal sepsis</td>
<td>Nov 16</td>
<td>Nov 16</td>
<td>ADT¶</td>
<td>Died</td>
<td>A</td>
</tr>
<tr>
<td>6/38/M</td>
<td>Oncology (MD)</td>
<td>Head and neck tumor</td>
<td>Nov 20, Nov 26</td>
<td>Nov 20, Nov 23</td>
<td>ADT, implanted medication port removed and replaced</td>
<td>Survived</td>
<td>A</td>
</tr>
<tr>
<td>7/38/M</td>
<td>SICU (CA)</td>
<td>Temporal lobe hemorrhage</td>
<td>Oct 29</td>
<td>Oct 29</td>
<td>ADT</td>
<td>Survived</td>
<td>NA¶</td>
</tr>
<tr>
<td>8/59/M</td>
<td>SICU (CA)</td>
<td>Enterocutaneous fistula; aortobifemoral bypass surgery</td>
<td>Nov 8</td>
<td>Nov 8</td>
<td>ADT</td>
<td>Survived</td>
<td>NA¶</td>
</tr>
</tbody>
</table>

*All infections (except in patient 1) developed after administration of intravenous fentanyl compounded at an out-of-state pharmacy; MD, Maryland; CA, California; NCCU, neurologic critical care unit; MICU, medical intensive care unit; SICU, surgical intensive care unit; NA, not applicable; ADT, antimicrobial drug therapy; MRSA, methicillin-resistant *Staphylococcus aureus*; PFGE, pulsed-field gel electrophoresis.

†Intravenous fentanyl in 0.9% sodium chloride solution from a 250-mL (10 µg/mL) bag prepared at compounding pharmacy A.

‡Strain A is the outbreak strain that was indistinguishable by PFGE from the fentanyl isolates.

¶The patient died of Group A streptococcal sepsis before the blood culture results for *S. paucimobilis* became available.

¶Isolates from patients 7 and 8 in the California hospital were not available for strain typing.
a central vascular access team. No growth occurred from cultures of 50 noninoculated activated charcoal blood culture bottles; this finding was therefore not consistent with a pseudo-outbreak or intrinsic contamination of the bottles. Pharmacy records showed that 5 (83%) of 6 case-patients had received at least 1 intravenous dose of fentanyl (10 μg/mL in 250 mL 0.9% sodium chloride) within the 48 hours before *S. paucimobilis* bacteremia developed. No other common exposure was identified. We found that our hospital had outsourced preparation of 250-mL fentanyl bags to pharmacy A, which shipped several lots to the hospital every 2 weeks.

Cultures of unopened samples from 1 implicated fentanyl lot grew *S. paucimobilis* that had a PFGE pattern indistinguishable from that of the isolates of the 5 patients who had received intravenous fentanyl (Figure 2). A sixth case-patient (patient 1; Table 2), who did not receive intravenous fentanyl, had *S. paucimobilis* with a unique PFGE pattern. Of 26 unopened bags from the implicated lot of fentanyl that were cultured, 16 (62%) grew *S. paucimobilis*. Cultures of 9 samples from 3 other fentanyl lots in use during the outbreak period produced no growth.

CDC’s multistate case-finding investigation determined that pharmacy A had distributed the contaminated fentanyl lot to 4 hospitals in different states. A California hospital that had received the implicated lot subsequently identified 2 additional case-patients who had *S. paucimobilis* bacteremia after administration of intravenous fentanyl from pharmacy A (Table 2). After diagnosis of bacteremia, these 2 case-patients received treatment with appropriate antimicrobial drugs without removal of existing central lines and were subsequently discharged from the hospital without complications from the bacteremia. At the California hospital, no unopened bags of the implicated fentanyl lot were available for culture, and the bloodstream isolates were not available for PFGE analysis. Specific lot numbers of fentanyl administered to patients were not available at either hospital. The 2 other hospitals that had received the implicated fentanyl lot did not detect any case-patients. The outbreak ended after the implicated fentanyl lot was removed from clinical areas. All bags of the implicated lot that could be located were tested for sterility at The Johns Hopkins Hospital and CDC before being discarded. The rest of the lot had either been used or was expired and destroyed. No product was recalled by pharmacy A.

Investigation found no evidence of tampering with or diversion of fentanyl within the Maryland hospital. We found stringent procedures in place to document and secure the narcotic chain of custody. No signs of tampering were visible on implicated bags of fentanyl that later grew *S. paucimobilis*, and the bags contained the expected concentration of fentanyl. We found that it was possible, although difficult, to remove and replace safety seals on the bags, which potentially could allow diversion of fentanyl without visible signs of tampering. Analysis of personnel access records from the automated medication and supply management system (Pyxis, Cardinal Health) did not identify any 1 person who had accessed >1 of the machines where the fentanyl was stored in the 4 hospital units with case-patients.

These 250-mL bags of intravenous fentanyl in 0.9% sodium chloride solution (10 μg/mL) are currently available only from pharmacy A and 1 other out-of-state compounding pharmacy. This preparation is the most frequently used at our institution and is not available from any pharmaceutical manufacturer. Because commercially available opioid alternatives at the desired concentration are not available, and to avoid disruption of patient care, our hospital continued to purchase the compounded preparation from pharmacy A. For 3 months after the outbreak, our microbiology laboratory performed sterility testing by culturing samples from each fentanyl lot received. None of
Sphingomonas paucimobilis

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( and is inconsistent with traditional pharmacy compounding
tions in response to bulk orders constitutes manufacturing
de the high-volume production of pharmaceutical prepara-
dations, the FDA has warned compounding pharmacies that
quality drugs. In response to other infectious outbreak inci-
des that they have the capacity to consistently produce high-
ded and had isolates with a PFGE pattern indistinguishable from that of fentanyl isolates. Patient 1
did not receive intravenous fentanyl and had S. paucimobilis
acteremia with a distinct PFGE pattern.

these samples grew any bacterial or fungal pathogens. We
do not have access to the results of FDA’s investigation
into compounding practices at pharmacy A.

Discussion

We describe a multistate outbreak of S. paucimobilis
acteremia that was associated with contaminated intra-
venous fentanyl prepared at an out-of-state compounding
armacy. Astute observation by microbiology laboratory
staff, good communication, and swift implementation of
an epidemiologic investigation led to expeditious charac-
terization of the source of the infections and termination
of the outbreak. Pharmacy A prepares large quantities of
compounded pharmaceutical preparations and distributes
them to many states in anticipation of orders. In contrast
to pharmaceutical manufacturers, traditional compounding
pharmacies are not routinely inspected by FDA to ensure
that they have the capacity to consistently produce high-
quality drugs. In response to other infectious outbreak inci-
dents, the FDA has warned compounding pharmacies that
the high-volume production of pharmaceutical prepara-
tions in response to bulk orders constitutes manufacturing
and is inconsistent with traditional pharmacy compounding
(17,18). Current good manufacturing practice regulations,
as defined by FDA, require end-product sterility testing,
among other stringent controls, when sterile pharmaceuti-
cal products are manufactured (19). Although traditional

pharmacy compounding fills a commercial void when
FDA-approved, commercially available drugs cannot meet
patients’ medical needs, the lack of end-product sterility
testing and other standards of good manufacturing practice
is a serious potential threat to patient safety when com-
pounding pharmacies produce and distribute large quan-
tities of sterile pharmaceutical preparations. Multistate
distribution of compounded preparations makes outbreaks
and clusters of infections even more difficult to detect and
manage.

In 2001, as a result of a dispute over advertising re-
lstrictions, the Supreme Court ruled that the compounding
provisions of the FDA Modernization Act of 1997 were
unconstitutional (20–22). In 2002, the FDA issued guid-
ance to clarify the FDA’s position on pharmaceutical
compounding; the guidance identified factors that are con-
sidered in deciding whether to initiate enforcement action
with respect to compounding (1). FDA historically has not
taken enforcement actions against pharmacies engaged in
traditional pharmacy compounding, but it has directed its
enforcement against establishments whose activities are
normally associated with a drug manufacturer. However,
much of the investigation, regulation, and enforcement of
compounding falls to state licensing boards (2,18). The
American Society of Health-System Pharmacists (ASHP),
the United States Pharmacopeia (USP), and the National
Association of Boards of Pharmacy have issued practice
and quality assurance guidelines for sterile compounding
of pharmaceutical preparations (23,24). In 2004, USP
chapter 797 put forth a set of enforceable standards for
the compounding of sterile preparations (25); recently
vised standards took effect on June 1, 2008 (24). These
standards do not require end-product sterility testing for
most compounded preparations (24). Some states require
compounding pharmacies to comply with USP 797 and
ASHP standards; however, a national survey found that
many pharmacies are not fully compliant with ASHP qual-
ity assurance guidelines (26), and a 2006 survey docu-
mented incomplete awareness and implementation of USP
797 standards (27). From 1990 through 2002, the FDA
received reports of >55 quality problems associated with
 compounded preparations (28); Table 1 shows reports of
6 such incidents published since 2002. An FDA survey in
2001 found 34% of tested preparations from compounding
pharmacies failed to meet analytic testing standards,
although none failed sterility tests (28).

Our investigation had limitations. Neither hospital
could trace the lot numbers administered to each patient, so
we could neither confirm which patients received contami-
nated lots of fentanyl nor assess an attack rate for receipt of
the contaminated lots. We did not conduct a case–control
study to calculate an odds ratio for administration of fen-
tanyl being the primary risk factor for infection. Isolates
from California case-patients were not available for strain typing. Finally, we do not have access to FDA’s investigational findings regarding pharmacy A, which might indicate the source of the contamination. Despite these limitations, the available evidence strongly suggests that contaminated fentanyl from pharmacy A was the source of this multistate outbreak of *S. paucimobilis* bloodstream infections.

FDA continues to face many serious and complex challenges (29,30). Our investigation, along with other similar published reports, indicates that the issue of large-scale pharmaceutical production and distribution by compounding pharmacies is also an urgent concern that requires attention. Pharmacies that compound and distribute large quantities of sterile pharmaceutical preparations without prescriptions for individual patients should be considered manufacturers and should be required to follow good manufacturing practices, including end-product sterility testing.

Until stricter regulations are imposed and enforced, hospital pharmacists and administrators must be cautious when outsourcing compounded pharmaceutical preparations and should consider the possibility of contaminated sterile pharmaceutical products when unusual organisms or patterns of disease are detected. Hospital personnel may be unaware that preparation of pharmaceutical products has been outsourced to a compounding pharmacy (3) and may not recognize the different regulatory requirements and potential implications of this decision. Healthcare facilities should strongly consider recording lot numbers of compounded medications administered to individual patients because this would aid investigations. Increased outsourcing of compounded pharmaceutical preparations makes surveillance for unexpected untoward events increasingly important. Compounding pharmacies should adhere to the standards set forth in USP 797 and should adopt more stringent quality control measures, including prerelease product testing, when preparing and distributing large quantities of sterile preparations.

Acknowledgments

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Dr Maragakis is an assistant professor of medicine in the Division of Infectious Diseases at the Johns Hopkins University School of Medicine. She is also an associate hospital epidemiologist at The Johns Hopkins Hospital. Her research interest is healthcare-associated gram-negative infections.

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**Article Title**

*Sphingomonas paucimobilis* Bloodstream Infections Associated with Contaminated Intravenous Fentanyl

**CME Questions**

1. Which of the following organisms is most likely to have been reported as a contaminant associated with betamethasone injection?

   A. *Sphingomonas paucimobilis*
   
   B. *Serratia marcescens*
   
   C. *Pseudomonas putida*
   
   D. *Exophiala* spp.

2. Which of the following is least likely to be an accurate description of *S. paucimobilis*?

   A. Gram-positive
   
   B. Glucose-nonfermenting
   
   C. Yellow-pigmented
   
   D. Found in soil and water

3. In this case series, which of the following was investigated as a source of exposure to fentanyl that resulted in *S. paucimobilis* bacteremia infection in patients?

   A. Intravenous infusions
   
   B. Contrast agents
   
   C. Medications
   
   D. All of the above

4. Which of the following strategies was recommended by the study authors to reduce the incidence of bacterial contamination by compounding pharmacies?

   A. Inspect source of drugs before preparation
   
   B. End-product sterility testing
   
   C. Elimination of compounding pharmacies
   
   D. None of the above

**Activity Evaluation**

<table>
<thead>
<tr>
<th>1. The activity supported the learning objectives.</th>
<th>Strongly Disagree</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>Strongly Agree</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. The material was organized clearly for learning to occur.</td>
<td>Strongly Disagree</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>Strongly Agree</td>
<td>5</td>
</tr>
<tr>
<td>3. The content learned from this activity will impact my practice.</td>
<td>Strongly Disagree</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>Strongly Agree</td>
<td>5</td>
</tr>
<tr>
<td>4. The activity was presented objectively and free of commercial bias.</td>
<td>Strongly Disagree</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>Strongly Agree</td>
<td>5</td>
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