

**NOT PRECEDENTIAL**

UNITED STATES COURT OF APPEALS  
FOR THE THIRD CIRCUIT

---

No. 16-2240

---

UNITED STATES OF AMERICA

v.

NORIAN CORPORATION; SYNTHES, INC.,  
Appellants

---

On Appeal from the United States District Court  
for the Eastern District of Pennsylvania  
(Criminal No.: 2:09-cr-00403-001 and 2:09-cr-00403-002)  
District Judge: The Honorable Legrome D. Davis

---

Submitted Pursuant to Third Circuit L.A.R. 34.1(a)  
July 14, 2017

Before: SMITH, *Chief Judge*, NYGAARD, and FUENTES, *Circuit Judges*

(Opinion Filed: September 8, 2017)

---

OPINION\*

---

FUENTES, *Circuit Judge*.

In 2003 and 2004 two patients died during spine surgery where bone cement manufactured by the defendants, Norian Corporation and its parent company, Synthes,

---

\* This disposition is not an opinion of the full Court and pursuant to I.O.P. 5.7 does not constitute binding precedent.

Inc. (collectively “Synthes”), were used. These and other deaths led the government to initiate a criminal investigation into Synthes’s marketing practices. This investigation culminated in the empaneling of a grand jury in the Eastern District of Pennsylvania, and Synthes, as well as several of its high-level executives, pled guilty to unlawful off-brand marketing of its bone cement in violation of the Food, Drug, and Cosmetic Act. In 2014, the estates of the two patients who died in 2003 and 2004 filed a civil wrongful death lawsuit in California state court against Synthes and its executives. In preparing for its defense, Synthes petitioned the court for certain grand jury materials. The District Court denied Synthes’s petition for failure to demonstrate a particularized need. Because we find that the District Court did not abuse its discretion, we will affirm.

## I.

Between the late 1990s and the early 2000s, Synthes manufactured and marketed two generations of bone cement called Norian SRS (“Skeletal Repair System”) and Norian XR, for use in orthopedic surgeries to fill bone voids. The Food and Drug Administration (“FDA”) approved these medical devices for use as a general bone filler, but expressly did not approve their use in spines, and required a warning that it should not be used in such a way on its label. Despite this clear directive from the FDA, however, Synthes nonetheless marketed its bone cement for use in vertebroplasty, a surgical procedure that treats fractures of the spine.

This off-label use, at the encouragement of Synthes sales representatives, led to several patient deaths and spurred a criminal investigation of Synthes and several high-level executives. After a grand jury proceeding in 2009, the government charged Synthes

and the executives with conspiracy to defraud the federal government,<sup>1</sup> and charged Synthes with criminal violations of the Food, Drug, and Cosmetic Act.<sup>2</sup> All defendants pled guilty to all charges, and the individuals were sentenced in November 2011.

In 2014, the estates of two of the patients who died during vertebroplasties in 2003 and 2004 filed a wrongful-death action in California state court against Synthes and several of its former executives. The plaintiffs allege that the decedents' deaths were caused by the off-label use of Norian SRS and Norian XR in their vertebroplasties, and that the bone cement would not have been used but for Synthes's assurance that the products were FDA-approved for this particular indication. During discovery for that case, one of the treating surgeons, Dr. Nottingham, testified in a deposition that he specifically recalls being told by both a Synthes sales representative and a Synthes executive that Norian XR was FDA-approved for use in vertebroplasties. He further testified that, as a result of this reassurance, he used the bone cement in the vertebroplasty for one of the decedents, despite the warning on the label that it should not be so used.

Seeking to undermine this testimony, Synthes petitioned the court for certain grand jury materials in the hope that they will contradict, or at least call into question, the reliability of Dr. Nottingham's recollection of the events that occurred over a decade ago. After reviewing the grand jury materials at issue *in camera*, the District Court denied the

---

<sup>1</sup> 18 U.S.C. § 371.

<sup>2</sup> 18 U.S.C. § 331.

petition.<sup>3</sup> Synthes moved for reconsideration, which was also denied. Synthes timely appealed both orders.<sup>4</sup>

### III.<sup>5</sup>

It is long established that, “in order to preserve the freedom and integrity of the deliberative process” during grand jury proceedings, Rule 6(e) protects from disclosure “matters occurring before the grand jury.”<sup>6</sup> The “policy of secrecy is not absolute,” however.<sup>7</sup> Disclosures may be granted “preliminary to or in connection with a judicial

---

<sup>3</sup> We have requested the materials that the District Court reviewed *in camera* and took them into consideration.

<sup>4</sup> Though Synthes’s petition was filed under a *criminal* rule of procedure on a *criminal* docket, we nonetheless conclude that Federal Rule of Appellate Procedure 4(a)(4), tolling the time for appeal in a civil case until after disposition of a motion for reconsideration, applies. “Proceedings to enforce civil rights are civil proceedings, and proceedings for the punishment of crimes are criminal proceedings.” *Ex Parte Tom Tong*, 108 U.S. 556, 559 (1883). Here, the only pending issue is whether grand jury materials may be disclosed to Synthes to help it defend itself in a separate civil action—an undoubtedly civil “right” though it implicates criminal rules of procedure. *In re Special Grand Jury 89-2*, 450 F.3d 1159, 1169 (10th Cir. 2006); *United States v. Campbell*, 294 F.3d 824, 827 (7th Cir. 2002); *United States v. Miramontez*, 995 F.2d 56, 58 (5th Cir. 1993).

<sup>5</sup> We have jurisdiction over the appeal under 28 U.S.C. § 1291, which we review for abuse of discretion. *Wiest v. Lynch*, 710 F.3d 121, 128 (3d Cir. 2013); *United States v. McDowell*, 888 F.2d 285, 289 (3d Cir. 1989). An abuse of discretion occurs when the District Court applies an “errant conclusion of law, an improper application of law to fact, or a clearly erroneous finding of fact.” *Wiest*, 710 F.3d at 128.

<sup>6</sup> *In re Grand Jury Investigation (N.J. State Comm’n of Investigation)*, 630 F.2d 996, 1000 (3d Cir. 1980) (hereinafter “SCF”).

<sup>7</sup> *Id.*

proceeding,”<sup>8</sup> so long as the requesting party can demonstrate “a particularized need for that information which outweighs the public interest in secrecy.”<sup>9</sup>

In its initial petition, Synthes requested (1) “Grand Jury testimony and memoranda of interviews of Dr. Paul Nottingham and Dr. Hieu Ball (the ‘Doctors’) and S. Michael Sharp (‘Dr. Sharp’);” (2) “documents produced to the Grand Jury by the Doctors or reviewed by the Doctors during the Grand Jury proceedings;” and (3) “documents reviewed by Dr. Sharp in preparation for or during the Grand Jury proceedings.”<sup>10</sup> The District Court denied this petition in part.

Synthes, on a motion for reconsideration, brought a different, more refined petition. Instead of asking for *all* grand jury testimony and interview memoranda, it sought only portions of Dr. Nottingham’s interview memoranda and grand jury testimony reflecting his understanding of the FDA status of the bone cement at the time of the surgery. And instead of *all* documents the Doctors produced to the grand jury, now it sought only “copies of any medical records, doctors’ notes, calendar appointments or other documents dated prior to the initiation of the grand jury investigation that were produced by Drs. Nottingham or Ball to the grand jury.”<sup>11</sup> The District Court denied this motion for reconsideration because “[n]one of the narrow reasons for granting

---

<sup>8</sup> Fed. R. Crim. P. 6(e)(3)(E)(i).

<sup>9</sup> *United States v. McDowell*, 888 F.2d 285, 289 (3d Cir. 1989) (internal citations and quotations omitted).

<sup>10</sup> A 76.

<sup>11</sup> A 235. Because the District Court granted disclosure of “any business records belonging to [Synthes], which Sharp returned to the” government, A 24, it dropped its third request for all documents reviewed by Dr. Sharp.

reconsideration,”<sup>12</sup> which are limited to “correct[ing] a clear error of law or [] prevent[ing] a manifest injustice in the District Court’s original ruling,”<sup>13</sup> applied.

On appeal, Synthes brings three arguments: first, that the portions of the interview memoranda that were not disclosed to the grand jury are not subject to grand jury secrecy under Rule 6(e); second, that business records, even though they were examined by the grand jury, are not subject to Rule 6(e) because they were independently created; and third, the District Court erred in finding that it has not demonstrated a particularized need for these documents. We disagree.

First, we reject Synthes’s argument that memoranda of interviews conducted in preparation for a grand jury investigation are not subject to grand jury secrecy so long as they were not presented to the grand jury. Rule 6(e) extends grand jury secrecy to all “[r]ecords, orders, and subpoenas *relating to* grand-jury proceedings.”<sup>14</sup> The touchstone is not what has been examined by the grand jury, but what may reveal “the essence of what takes place in the grand jury room.”<sup>15</sup> The District Court, after reviewing the

---

<sup>12</sup> A 28.

<sup>13</sup> *Id.* (quoting *United States v. Dupree*, 617 F.3d 724, 732 (3d Cir. 2010)).

<sup>14</sup> Fed. R. Crim. P. 6(e)(6) (emphasis added).

<sup>15</sup> *SCI*, 630 F.2d at 1000; see *In re Grand Jury Matter (Garden Court Nursing Home, Inc.)*, 697 F.2d 511, 512-13 (3d Cir. 1982) (finding that prosecution summaries of the defendant’s books and records are subject to grand jury secrecy because the conclusions were likely revealed to the grand jury and because these summaries do not exist independently of the grand jury process); *United States v. Ulbricht*, 858 F.3d 71, 107 (2d Cir. 2017) (finding that a letter describing a grand jury investigation—which was not presented to a grand jury—nonetheless falls under Rule 6(e)). *But see In re Grand Jury Matter (Catania)*, 682 F.2d 61, 64 (3d Cir. 1982) (finding that materials that were the product of an FBI investigation, that “were not generated by the grand jury, and were not requested or subpoenaed by the grand jury,” and were likely not ever presented before the grand jury are not subject to grand jury secrecy rule).

requested documents *in camera*, concluded “the information contained in the memoranda relates to what transpired before the grand jury.”<sup>16</sup> Having reviewed the same documents *in camera*, we concur in the District Court’s finding.

Second, we similarly reject Synthes’s argument that the medical records it seeks fall outside the secrecy requirements of Rule 6(e). It is true that “business records . . . created for purposes independent of grand jury investigations,” which “have many legitimate uses unrelated to the substance of the grand jury proceedings,” are not subject to Rule 6(e) merely because they were reviewed by a grand jury.”<sup>17</sup> And we have granted disclosure of documents presented to grand juries “[w]hen testimony or data is sought for its own sake—for its intrinsic value in the furtherance of a lawful investigation—rather than to learn what took place before the grand jury.”<sup>18</sup>

But that is not the request before us. Synthes did not simply request business and medical records generated by Dr. Nottingham and Dr. Ball, which only incidentally were presented to a grand jury. Instead, Synthes sought *only* documents “produced to the Grand Jury.”<sup>19</sup> This is precisely the type of “general request for all documents collected or received in connection with” a grand jury investigation that “would be in effect a disclosure of the grand jury proceedings.”<sup>20</sup> Synthes’s requests make clear that the

---

<sup>16</sup> A 34.

<sup>17</sup> *SCI*, 630 F.2d at 1000.

<sup>18</sup> *Id.* at 1001 (quoting *United States v. Interstate Dress Carriers*, 280 F.2d 52, 54 (2d Cir. 1960)).

<sup>19</sup> A 76; A 235.

<sup>20</sup> *United States v. Stanford*, 589 F.2d 285, 291 n.6 (7th Cir. 1978).

documents are not sought for their own intrinsic value; their significance lies only in their significance to the grand jury.<sup>21</sup>

Having decided that all of the documents sought are subject to Rule 6(e), we now turn to Synthes's third argument: the District Court erred in finding that Synthes did not carry its burden of demonstrating "particularized need that outweighs the public's interest in secrecy."<sup>22</sup> To prove particularized need, the party must demonstrate that (1) "the material they seek is needed to avoid a possible injustice in another judicial proceeding;" (2) "the need for disclosure is greater than the need for secrecy;" and (3) "their request is structured to cover only the materials so needed."<sup>23</sup>

As Synthes correctly asserts, the Supreme Court has recognized that "the typical showing of particularized need arises when a litigant seeks to use the 'grand jury transcript at the trial to impeach a witness, to refresh his collection, to test his credibility and the like,'" so as to "avoid misleading the trier of fact."<sup>24</sup> However, the mere incantation that the requested materials are needed to impeach a witness is not enough. The moving party must point to actual inconsistencies that could be remedied by the requested grand jury materials, the disclosure of which is needed to avoid possible injustice in the separate judicial proceeding.<sup>25</sup> In determining whether particularized

---

<sup>21</sup> *Id.*

<sup>22</sup> *McDowell*, 888 F.2d at 289.

<sup>23</sup> *Douglas Oil v. Petrol Stops Nw.*, 441 U.S. 211, 222 (1979).

<sup>24</sup> *Id.* at 222 n.12 (quoting *Untied States v. Procter & Gamble Co.*, 356 U.S. 677, 683 (1958)).

<sup>25</sup> See *In re Special Grand Jury 89-2*, 143 F.3d 565, 571 (10th Cir. 1998); *In re Grand Jury Testimony (Doe)*, 832 F.2d 60, 63 (5th Cir. 1987); *United States v. Fischbach &*



need has been demonstrated and whether that need outweighs the public need for secrecy, the District Court is afforded substantial discretion.<sup>26</sup>

Based on the record, we conclude that the District Court’s denial of the petition was not an abuse of discretion. Three reasons support this conclusion. First, we agree with the District Court that Synthes failed to convincingly point to an actual inconsistency warranting disclosure of grand jury materials to avoid possible injustice. The alleged discrepancy is between Dr. Nottingham’s deposition testimony that an “unspecified executive expressly reassured him that the proposed use [of the bone cement in vertebroplasty] was ‘on-label,’” and the absence of reference to this conversation in the contemporaneous documents recounting the aftermath of the surgery.<sup>27</sup> This is not an actual discrepancy. These documents were Synthes’s records put together by product development that were primarily concerned about the medical reasons for a fatality—hardly the place to document an incriminating conversation. Even so, one document notes that “[t]he surgeon denied any knowledge of Norian XR being in its Limited Release/Test Market Phase. . . . He claimed the sales consultant ‘pushed’ this product on

---

*Moore, Inc.*, 776 F.2d 839, 845 (9th Cir. 1985); *United States v. Silva*, 745 F.2d 840, 846 (4th Cir. 1984).

<sup>26</sup> *Douglas Oil*, 441 U.S. at 222.

<sup>27</sup> Petitioner Br. at 20-21; A 138-139.

him and was unclear as to its status on the market.”<sup>28</sup> This appears to be consistent with the main thrust of Dr. Nottingham’s deposition testimony.

Second, we are not persuaded that the requested grand jury material is truly the only source of information that could elucidate “whether [Synthes] misled Dr. Nottingham about [] Norian XR.”<sup>29</sup> Dr. Nottingham testified that he spoke to two people at Synthes about the FDA status of the bone cement—a sales representative who attended the surgery and an executive with whom he spoke over the phone. Surely those individuals may be able to shine some light on what occurred. Furthermore, the nurse who assisted in the surgery and was the one who finally read aloud the warning label on the Norian XR may also have valuable information. We have no doubt that the requested grand jury materials are relevant, and maybe even helpful, but “[t]he rule governing disclosure of grand jury testimony ‘is not to be used as a substitute for general discovery.’”<sup>30</sup>

Finally, even if Synthes has demonstrated some need for the requested materials,<sup>31</sup> the District Court did not abuse its discretion in finding that its need does not outweigh

---

<sup>28</sup> A 229.

<sup>29</sup> *Id.*

<sup>30</sup> *In re Lynde*, 922 F.2d 1448, 1453-54 (10th Cir. 1991) (quoting *United States v. Evans & Assocs. Const. Co., Inc.*, 839 F.2d 656, 658 (10th Cir. 1988)).

<sup>31</sup> We note that Synthes failed, in its initial petition, to “structure[] [its request] to cover only material so needed.” *Douglas Oil*, 441 U.S. at 222. It attempted to rectify this problem on its motion for reconsideration by submitting a narrower request. However, a motion for reconsideration is simply not the appropriate vehicle to bring what is essentially a new request; these motions are limited to “correct[ing] a clear error of law or [] prevent[ing] a manifest injustice in the District Court’s original ruling.” *Dupree*, 617 F.3d at 732.

the public's need for secrecy. The grand jury investigation at issue here has been concluded for many years, and while "the interests in grand jury secrecy [are] reduced," they "are not eliminated."<sup>32</sup> "For in considering the effects of disclosure on grand jury proceedings, the courts must consider not only the immediate effects upon a particular grand jury, but also the possible effect upon the functioning of future grand juries."<sup>33</sup> The interest in secrecy in this case remains great. Synthes is hoping to use grand jury materials to undermine the credibility of Dr. Nottingham, a key witness during the grand jury proceeding, and to impliedly shift blame for the death of his patient to him, away from Synthes. This is precisely the kind of "future retribution" that could chill the candor of future grand jury witnesses. While this need for secrecy is not insurmountable, it has not been overcome in this case.

#### IV.

For the foregoing reasons, we will affirm the District Court's orders.

---

<sup>32</sup> *Douglas Oil*, 411 U.S. at 222.

<sup>33</sup> *Id.*