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## FOREWORD

### **A ROT IN HEAVEN** A POWERFUL INVESTIGATIVE PARTNERSHIP, THE OPIOID CRISIS, PILL PROFITS, AND A PULITZER PRIZE

*Becky L. Jacobs\**

“Almost Heaven, West Virginia”

*Bill Danoff, Taffy Nivert, and John Denver*<sup>1</sup>

“All the host of heaven shall rot away, and the skies roll up like a scroll.”

*Isaiah 34:4*<sup>2</sup>

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In the spring of 2018, when the *Tennessee Journal of Law and Policy* hosted the “Healing Appalachia: The Role of Professionals in Solving the Opioid Crisis” symposium, there were more than 400 lawsuits pending against corporations that manufacture, distribute, and retail opioids in just *one* consolidated case in the federal

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<sup>1</sup> Bill Danoff, Taffy Nivert & John Denver, *Take Me Home, Country Roads* (April 12, 1971).

<sup>2</sup> *Isaiah* 34:4 (English Standard Version).

district court for the Northern District of Ohio.<sup>3</sup> This single, consolidated case initially involved only claims brought by governmental entities, but the Judicial Panel on Multidistrict Litigation consolidating the cases acknowledged that the action potentially could include claims brought by individuals, consumers, hospitals, and third party payors, as well as additional categories of defendants.<sup>4</sup>

It is not hyperbole to say that we can thank Eric Eyre of the Charleston Gazette-Mail, of Charleston, West Virginia, for these lawsuits and for the momentum that we now are experiencing in support of a response to the national opioid crisis. The government, the legal community, and many media outlets seemingly were willing to ignore the opiate plague that was infecting our communities, but Eric's Pulitzer Prize-winning series of articles<sup>5</sup> made it impossible for anyone to profess ignorance any longer.

As lawyers, we also should take pride in the role that our colleagues from WVU College of Law, Pat McGinley and Suzanne Weise, played in supporting Eric's efforts to uncover the shocking data that appeared

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<sup>3</sup> *In re Nat'l Prescription Opiate Litig.*, MDL No. 1:17-MD-2804 (N.D. Ohio 2017) [hereinafter "MDL Litigation"]; see also Jan Hoffman, *Can This Judge Solve the Opioid Crisis?*, N.Y. TIMES (Mar. 7, 2018), <https://www.nytimes.com/2018/03/05/health/opioid-crisis-judge-lawsuits.html> [<https://perma.cc/H87X-UYNW>].

<sup>4</sup> Transfer Order, *In re Nat'l Prescription Opiate Litig.*, MDL No. 1:17-MD-2804 (N.D. Ohio Dec. 12, 2017).

<sup>5</sup> Eric also won the Scripps Howard First Amendment Award, was a finalist for the Selden Ring awards, and won a first-place award for investigative reporting from the Association for Healthcare Journalists. See Susan Heavey, *Reporter's Work Pushes Regulators, Legislators to Act on Opioids*, ASS'N HEALTH CARE JOURNALISTS: COVERING HEALTH (May 8, 2017), <https://healthjournalism.org/blog/2017/05/reporters-work-pushes-regulators-legislators-to-act-on-opioids/> [<https://perma.cc/MDV6-FF6W>].

in his articles. Without their tireless efforts, Eric may not have been able to prevail against the well-financed political and industry resistance to accessing the data that so starkly revealed the appalling opiate prescription and distribution patterns in West Virginia.

To put the importance of Eric's contribution, and that of Pat and Suzanne, in perspective, consider the odds against which they were fighting - and it is critical to remember that, at the time Eric, Pat, and Suzanne were seeking the distribution data, the only litigation pending against any entity or individual involved in the opioid distribution chain was the groundbreaking lawsuit filed by then-West Virginia Attorney General Darrell McGraw in 2012 against Cardinal Health.<sup>6</sup> Eric's newspaper, the Gazette-Mail, was a family-owned, daily newspaper with a print circulation of 37,000, and Pat and Suzanne were providing their services pro bono.

Thus, the odds were enormous, considering the Goliath-like financial resources of their opposition. Opioid painkillers are a nearly \$9 billion-a-year market in the U.S. alone,<sup>7</sup> and pharmaceutical companies such as Purdue Pharma L.P., Johnson & Johnson, Teva, Allergan PLC, and the Endo Health Solutions unit of Endo International PLC have all earned billions over the years from the sale of these drugs.<sup>8</sup> Wholesale distributors like McKesson Corp., Cardinal Health, and AmerisourceBergen also have profited,<sup>9</sup> as have the

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<sup>6</sup> *See Records: Company Shipped Millions of Pills to West Virginia*, ASSOCIATED PRESS (Oct. 09, 2016), <https://www.apnews.com/20ed75eba921466aba2155f4a846dc75> [https://perm a.cc/P624-LN5W].

<sup>7</sup> Haley Sweetland Edwards, *The Drug Cascade*, TIME (June 22, 2017), <http://time.com/4828108/the-drug-cascade/> [https://perma.cc/Q9L5-A84S].

<sup>8</sup> *Stock Review: Two-Bagger Collegium Pharmaceutical Surges 108%*, GLOBAL ROUND UP - STOCKS, Mar. 23, 2018.

<sup>9</sup> Katie Tabeling, *County Files Lawsuit Against Opioid Manufacturers*, CECIL WHIG (Elkton, Md.) (Jan. 9, 2018), <http://www.cecildaily.com/spotlight/county-files-lawsuit->

physicians, pain clinics, and pharmacies prescribing and dispensing these medications - some legitimately, some not.<sup>10</sup>

These profits, though, have had a very high public health cost, as Eric's articles helped to expose. Here is just a snapshot of the scale of what is being called an epidemic<sup>11</sup> and what President Trump declared, in August of 2017, to be a "national emergency."<sup>12</sup> According

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against-opioid-manufacturers/article\_9be21338-13aa-5855-b8be-caf98167bf5f.html [https://perma.cc/Y2PV-RXFU] ("Among the lawsuit's 20 manufacturing defendants, 14 are subsidiaries of six pharmaceutical giants, including Endo, Purdue, Johnson & Johnson, Teva, Allegran [sic] and Mallinckrodt Pharmaceuticals. The remaining defendants are McKesson, Cardinal Health and AmerisourceBergen - characterized in the complaint as 'the big three' drug wholesale distributors."); see also Joey Garrison, *Nashville Sues Opioid Makers*, THE TENNESSEAN, Dec. 23, 2017, at A5, <https://www.tennessean.com/story/news/2017/12/23/nashville-sues-opioid-manufacturers-recoup-costs-fighting-epidemic/978861001/> [https://perma.cc/3CYT-3L8N] ("Cities like Nashville and their taxpayers have borne the cost of the opioid epidemic for far too long while the pharmaceutical manufacturing industry, consisting of manufacturers and distributors, has reaped astronomical profits[.]").

<sup>10</sup> Chris McGreal, *'It was a Conspiracy': Recovering Addicts Wage Legal Battle over Prescription Use*, GUARDIAN (UK) (Aug. 28, 2016), <https://www.theguardian.com/us-news/2016/aug/28/opioid-addiction-west-virginia-lawsuit> [https://perma.cc/Z2QP-HCJU] ("29 survivors of opioid addiction or relatives of those who overdosed on painkillers . . . accuse doctors, pharmacies and distributors in a rural corner of West Virginia of pushing the powerful and highly addictive drugs, which have properties similar to heroin.").

<sup>11</sup> U.S. DRUG ENF'T AGENCY, 2015 NATIONAL DRUG THREAT ASSESSMENT SUMMARY, at iii (2015), <https://www.dea.gov/docs/2015%20NDTA%20Report.pdf> [https://perma.cc/5USM-JQJS].

<sup>12</sup> Joel Achenbach, John Wagner & Lenny Bernstein, *Trump Says Opioid Crisis is a National Emergency, Pledges More*

to the CDC, more than 200,000 people in the U.S. died from overdoses related to prescription opioids from 1999 to 2016.<sup>13</sup> In 2016 alone, more than 46 people died *every day* from overdoses involving prescription opioids.<sup>14</sup> Also, in 2016, three of the six states with the highest rates of death due to drug overdose were located in close geographic proximity to Tennessee: West Virginia (52.0 per 100,000), Ohio (39.1 per 100,000), and Kentucky (33.5 per 100,000).<sup>15</sup> Tennessee's rate was 24.5.<sup>16</sup>

These death rates are startling, but perhaps not as surprising as one might first imagine given that doctors prescribed enough opioids in 2016 to provide every man, woman, and child in the U.S. with 36 pills each.<sup>17</sup> The highest prescribing rates, however, reportedly were concentrated in the more rural states that year, primarily in the South; in Tennessee, with the second highest prescribing rate in the nation, every resident could have had 70 pills each in 2016.<sup>18</sup>

The West Virginia numbers were even more alarming. Eric's research revealed that, "[i]n six years,

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*Money and Attention*, WASH. POST (Aug. 10, 2017), [https://www.washingtonpost.com/politics/trump-declares-opioid-crisis-is-a-national-emergency-pledges-more-money-and-attention/2017/08/10/5aaae32-7dfe-11e7-83c7-5bd5460fd7e\\_story.html](https://www.washingtonpost.com/politics/trump-declares-opioid-crisis-is-a-national-emergency-pledges-more-money-and-attention/2017/08/10/5aaae32-7dfe-11e7-83c7-5bd5460fd7e_story.html) [<https://perma.cc/GTU6-EMRN>].

<sup>13</sup> CTRS. FOR DISEASE CONTROL & PREVENTION, PRESCRIPTION OPIOID OVERDOSE DATA, <https://www.cdc.gov/drugoverdose/data/overdose.html> [<https://perma.cc/6HVX-YYKV>].

<sup>14</sup> *Id.*

<sup>15</sup> CTRS. FOR DISEASE CONTROL & PREVENTION, *Rates*, DRUG OVERDOSE DEATH DATA, <https://www.cdc.gov/drugoverdose/data/statedeaths.html> [<https://perma.cc/Y7SX-YVZK>].

<sup>16</sup> *Id.*

<sup>17</sup> PACIRA PHARM., INC., UNITED STATES FOR NON-DEPENDENCE: AN ANALYSIS OF THE IMPACT OF OPIOID OVERPRESCRIBING IN AMERICA 11 (2017), [https://www.pacira.com/sites/default/files/inline-files/USND\\_Stats\\_FINAL.pdf](https://www.pacira.com/sites/default/files/inline-files/USND_Stats_FINAL.pdf) [<https://perma.cc/JAS3-WDWP>].

<sup>18</sup> *Id.* at Slides 11-12.

drug wholesalers showered the state with 780 million hydrocodone and oxycodone pills, while 1,728 West Virginians fatally overdosed on those two painkillers[.]”<sup>19</sup> Proportionately, in terms of geographical distribution and in terms of population, that “amount[s] to 433 pain pills for every man, woman and child in West Virginia.”<sup>20</sup> In that state, the data that Eric secured uncovered a dismaying pattern of distribution: small, independent pharmacies received a disproportionate percentage of the shipments of prescription opioids, e.g., wholesale distributors delivered 1.4 million to 4.7 million hydrocodone pills each year to locally-owned pharmacies in Mingo and Logan counties when one of the busiest Wal-Mart’s in West Virginia received only about 5,000 oxycodone and 9,500 hydrocodone pills annually.<sup>21</sup>

The companies involved in the opioid distribution chain fought tooth-and-nail to keep these data from being released, relying upon an impressive array of legal talent to defend them on this issue<sup>22</sup> and on the other claims of, *inter alia*, negligence, public nuisance, violations of West Virginia’s consumer act, etc. that arose in that ground-

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<sup>19</sup> Eric Eyre, *Drug Firms Poured 780M Painkillers into WV amid Rise of Overdoses*, W.V. GAZETTE-MAIL (Dec. 16, 2016), [https://www.wv-gazette.com/news/cops\\_and\\_courts/drug-firms-poured-m-painkillers-into-wv-amid-rise-of/article\\_99026dad-8ed5-5075-90fa-adb906a36214.html](https://www.wv-gazette.com/news/cops_and_courts/drug-firms-poured-m-painkillers-into-wv-amid-rise-of/article_99026dad-8ed5-5075-90fa-adb906a36214.html) [<https://perma.cc/R38M-FFSP>].

<sup>20</sup> *Id.*

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

<sup>22</sup> AmerisourceBergen Drug Corp.’s Objection to Hearing Date and Opposition to Motion on Behalf of the Charleston Gazette to Intervene for the Limited Purpose of Moving the Circuit Court to Unseal the Plaintiff’s Second Amended Complaint at 5, State *ex rel.* Morrissey v. AmerisourceBergen Drug Corp., Civil Action No. 12-C-141 (W. Va. Cir. Ct. 2016) (“And if [the DEA] protect[s] any of that information from the intrusive journalistic nose of the Gazette, then its confidential nature must be respected.”).

breaking case filed against them in West Virginia.<sup>23</sup> Highly regarded national and West Virginia firms such as Jones Day; Morgan Lewis; Steptoe & Johnson; Jackson Kelly; Bowles Rice; and Spilman Thomas & Battle were involved as defense counsel in the West Virginia litigation.<sup>24</sup>

Pat, Suzanne, and Boone County, West Virginia lawyer Tim Conaway provided essential, legal support to the Gazette-Mail to force disclosure of the court records that revealed these staggering distribution figures.<sup>25</sup> The sealed complaint in the State's lawsuit contained shipment data supplied by defendants and the U.S. DEA during discovery in the case, and the West Virginia Attorney General at that time, Patrick Morrissey,<sup>26</sup> and

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<sup>23</sup> Complaint, State *ex rel.* McGraw v. AmerisourceBergen Drug Corp., Civil Action No. 12-C-141, 2012 WL 2544646 (W. Va. Cir. Ct. 2012).

<sup>24</sup> *See, e.g.*, Docket, West Virginia v. AmerisourceBergen, Civil Action No. 2:12-CV-03760 (Closed Mar. 27, 2013).

<sup>25</sup> *See supra* note 22. A conversation about these events between Pat and Eric took place at an event at Washington & Lee at <https://livestream.com/wlu/wv-opioid/videos/165654080>.

<sup>26</sup> It is not without irony that Morrissey, who is running for the U.S. Senate as an anti-opioid warrior, *see* Ken Blackwell, *A Clear Choice in WV Senate Battle: Conservative Patrick Morrissey*, TOWNHALL: OPINION (July 14, 2017), <https://townhall.com/columnists/kenblackwell/2017/07/14/a-clear-choice-in-wv-senate-battle-conservative-patrick-morrissey-n2354783> [<https://perma.cc/9LD5-JD55>], lobbied for the Healthcare Distribution Management Association, a group that represents drug wholesalers, in Washington, D.C. before taking office as West Virginia Attorney General in 2013; Cardinal Health is a member of this group. Louis Jacobson, *A Closer Look at Patrick Morrissey's Family Ties to 'Big Pharma'*, POLITIFACT (Mar. 27, 2018), <http://www.politifact.com/truth-o-meter/article/2018/mar/27/closer-look-patrick-morriseys-family-ties-big-phar/> [<https://perma.cc/S59G-3MBS>]. His wife, Denise Henry Morrissey, is a partner with a Washington lobbying firm retained by a number of major pharmaceutical

other plaintiffs apparently agreed with the defendants' arguments that the data were proprietary.<sup>27</sup> Pat et al. filed a motion on behalf of the Gazette-Mail to unseal the complaint, and, despite a vigorous and lengthy fight to maintain the confidentiality of the records, the judge ordered the first ever public release of these previously-undisclosed data.<sup>28</sup>

The import of this legal event cannot be overstated - these data shifted the public discourse on the opioid crisis. Opioid abuse was of course on the public radar, but opinion did not appear to have moved much beyond the "blame the addict" and "those damn pill mills" mentality. The data in the lawsuit, however, told stories of predatory practices and suffering people in pain, and they inspired a sense of outrage and urgency that prompted enforcement and reform efforts by regulators and legislators.<sup>29</sup>

In West Virginia alone, for example, Cardinal Health and AmerisourceBergen, two of the nation's "big three" drug wholesalers, agreed to pay the State a combined \$36 million to settle their lawsuits, and at least one county commission has filed suit against all of the "big three" to recover costs associated with prescription drug abuse, with other West Virginia counties and cities declaring their intentions to follow suit.<sup>30</sup> Beyond West

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clients, including several involved in the opioid industry, such as Allergan, Johnson & Johnson, Janssen, Purdue Pharma, and the membership of the Healthcare Leadership Council; e.g., Cardinal, Sanofi, Johnson & Johnson, and Pfizer. *Id.*

<sup>27</sup> Eric Eyre, *Drug Firms Fueled 'Pill Mills' in Rural WV*, W.V. GAZETTE-MAIL (May 23, 2016), [https://www.wvgazette.com/news/cops\\_and\\_courts/drug-firms-fueled-pill-mills-in-rural-wv/article\\_14c8e1a5-19b1-579d-9ed5-770f09589a22.html](https://www.wvgazette.com/news/cops_and_courts/drug-firms-fueled-pill-mills-in-rural-wv/article_14c8e1a5-19b1-579d-9ed5-770f09589a22.html) [<https://perma.cc/2B SG-3TFD>].

<sup>28</sup> *See id.*

<sup>29</sup> *See Heavey, supra* note 5.

<sup>30</sup> Eric Eyre, *2 Drug Distributors to Pay \$36M to Settle WV Painkiller Lawsuits*, W.V. GAZETTE-MAIL (Jan. 9, 2017), <https://www.wvgazette.com/news/health/drug->

Virginia's borders, nearly every state Attorney General has either filed a lawsuit against an opioid manufacturer or distributor or is involved in an investigation and has issued subpoenas for records.<sup>31</sup> The MDL litigation consolidated in the Northern District of Ohio currently involves 400 cases filed by cities, counties, and states against manufacturers and distributors of opiates, but those involved have publicly acknowledged the possibility that individuals, consumers, hospitals, and third party payors might be added as plaintiffs.<sup>32</sup> The

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distributors-to-pay-m-to-settle-wv-painkiller-lawsuits/article\_b43534bd-b020-5f56-b9f3-f74270a54c07.html [https://perma.cc/AVK9-TB9E].

<sup>31</sup> Jerry Mitchell, *Judge: Stop the Legal Fights and Curb the Opioid Epidemic*, CLARION LEDGER (Jan. 26, 2018), <https://www.clarion-ledger.com/story/news/2018/01/26/opioid-epidemic-litigation-dan-polster/1014046001/> [https://perma.cc/C7J6-82E9]. Tennessee Attorney General Herbert H. Slatery, III, for example, filed a 270-page complaint in the Knox County Circuit Court in May of 2018 alleging that Purdue Pharma, L.P. violated the Tennessee Consumer Protection Act vis-à-vis false, deceptive, and/or unsubstantiated claims about its opioid products or opioids in general including OxyContin; that it breached a 2007 Agreed Final Judgment with the State involving the cessation of sales promotions to prescribers whose practices showed indications of abuse or diversion; and that it created a public nuisance in Tennessee by significantly interfering with the commercial marketplace and endangered the life and health of the State's residents. *See* Tennessee's Motion, Memorandum in Support, and Order Granting Leave to File Complaint under Seal, State *ex rel.* Slatery v. Purdue Pharma, L.P., No. 1-173-18 (Tenn. Knox Co. Cir. Ct. 2018), <https://www.tn.gov/content/dam/tn/attorneygeneral/documents/foi/purdue/purdue-motion-5-15-2018.pdf> [https://perma.cc/S8E2-QDQC].

<sup>32</sup> *See supra* note 4. The Tennessee Attorney General was not, at the time of the publication of this Foreword, a party to the federal multidistrict litigation pending in Cleveland, Ohio, but that Office has publicly stated that it is "voluntarily engaging in settlement discussions" in connection therewith. *See* Press

lawsuits involve claims as widely divergent as public nuisance, negligence, negligent misrepresentation, fraud, and unjust enrichment as well as violations of consumer protection laws and the state versions of the Controlled Substances Act and RICO statute(s).<sup>33</sup>

The pool of defendants is also expanding. For example, attributing blame and seeking recovery even further afield, several cities in West Virginia brought a class action suit against the Joint Commission on Accreditation of Health Care Organizations on behalf of all U.S. cities and towns.<sup>34</sup> The Joint Commission is the entity that certifies U.S. health care organizations and programs. The suit alleges that the Joint Commission's Pain Management Standards "grossly misrepresented the addictive qualities of opioids and fostered dangerous pain control practices[.]"<sup>35</sup>

Outside of the civil context, prosecutors have begun to bring charges against individuals for crimes involving opioid abuse and distribution. In 2015, the Obama-era U.S. Department of Justice issued a memo directing federal prosecutors to pursue charges against individual defendants.<sup>36</sup> As an example of its use of this policy, the DOJ charged John Kapoor, former CEO of Insys Therapeutics, with conspiracy to commit racketeering and mail and wire fraud in connection with a bribe and kickback scheme associated with Subsys, the

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Release No. 18-10, Tenn. Attorney Gen., No. 18-10: Tennessee Attorney General Sues Purdue Pharma (May 15, 2018), <https://www.tn.gov/attorneygeneral/news/2018/5/15/pr18-10.html> [<https://perma.cc/R459-5ZP4>].

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

<sup>34</sup> Complaint, *City of Charleston v. The Joint Commission*, No. 2:17-cv-04267 (S.D.W.V. Nov. 2, 2017).

<sup>35</sup> *Id.* at 2.

<sup>36</sup> Memorandum from Deputy Att'y Gen. Sally Q. Yates on Individual Accountability for Corporate Wrongdoing (Sept. 9, 2015), <https://www.justice.gov/archives/dag/file/769036/download> [<https://perma.cc/8ARN-NPCS>].

company's powerful synthetic opioid fentanyl in spray form.<sup>37</sup> Closer to home, in early 2017, a Maryville doctor received a 10-year federal prison sentence for serving as the supervising and prescribing doctor at a notorious Maryville pain clinic.<sup>38</sup>

Legislative activity is also taking place in response to the momentum generated in the wake of Eric's articles. That activity, however, is focused primarily at the state level. As of April 2018, twenty-eight states had enacted legislation that either limited, offered guidance, or listed requirements related to opioid prescribing practices.<sup>39</sup> Further, every state except Missouri has enacted monitoring program legislation "designed to reduce doctor shopping and identify patients at risk for substance use disorders."<sup>40</sup> In addition to these

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<sup>37</sup> Cynthia McFaddin, *Billionaire Charged with Bribing Doctors to Prescribe Opioids*, NBC NEWS: HEALTH (Oct. 26, 2017), <https://www.nbcnews.com/storyline/americas-heroin-epidemic/billionaire-charged-bribing-doctors-prescribe-opioids-n814686> [<https://perma.cc/W3D3-L62U>] ("The corporation is not facing criminal charges and is still selling Subsys - some \$240 million worth of Subsys just last year.")

<sup>38</sup> Jamie Satterfield, *Doctor for Maryville Pill Mill Draws 10-year Prison Term*, KNOXVILLE NEWS SENTINEL (Feb. 22, 2017), <https://www.knoxnews.com/story/news/crime/2017/02/22/doctor-maryville-pill-mill-draws-10-year-prison-term/98268716/> [<https://perma.cc/437L-KJ5V>].

<sup>39</sup> *Prescribing Policies: States Confront Opioid Overdose Epidemic*, NAT'L CONF. ST. LEGISLATURES: STATE ACTION (Apr. 5, 2018), <http://www.ncsl.org/research/health/prescribing-policies-states-confront-opioid-overdose-epidemic.aspx> [<https://perma.cc/VR62-LA4U>].

<sup>40</sup> Chris Elkins, *The Opioid Epidemic: What Caused the Heroin Epidemic?*, DRUGREHAB.COM, <https://www.drugrehab.com/opioid-epidemic-causes/> [<https://perma.cc/ZX2U-NZ7J>]. The Prescription Safety Act of 2016 is Tennessee's version - legislation that revised or made permanent existing regulation of controlled substances and enacted several other provisions. Tennessee Prescription Safety Act of 2016, 2016 Tenn. Pub.

legislative initiatives, states have considered, proposed, and/or adopted opioid-related legislation in a number of other categories, including opioid taxes, pain clinic licensure, training and education plans, and pill “take-back” programs.<sup>41</sup>

At the federal level, one hears numerous claims that actions are being taken to “combat the opioid crisis[.]”<sup>42</sup> including President Trump’s plan to use the death penalty as an option for drug dealers in fatal opioid overdose cases.<sup>43</sup> Not all have been deemed to be a success. For example, an earlier piece of federal legislation, the Ensuring Patient Access and Effective Drug Enforcement Act of 2016, has been subjected to scathing criticism, with even its title described as “misleading.”<sup>44</sup> According to a report resulting from a joint investigation by The Washington Post and “60 Minutes,” an ex-DEA lawyer working for a pharmaceutical company drafted an early version of the

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Acts 1002 (codified at TENN. CODE ANN. §§ 53-10-301 to -312 (2016)).

<sup>41</sup> Kate Blackman & Amber Widgery, *Summer Progress in Opioid Misuse Prevention Legislation*, NAT’L CONF. ST. LEGISLATURES: NCSL BLOG (Aug. 31, 2017), <http://www.ncsl.org/blog/2017/08/31/summer-progress-in-opioid-misuse-prevention-legislation.aspx> [<https://perma.cc/PNT2-ZBM4>].

<sup>42</sup> See, e.g., *Combating the Opioid Crisis*, HOUSE COMM. ON ENERGY & COM.: ISSUE IN FOCUS, <https://energycommerce.house.gov/opioids/> [<https://perma.cc/V9DA-VNW9>].

<sup>43</sup> Louise Radnofsky, *Trump’s Opioid Battle Plan Includes Seeking More Death-Penalty Prosecutions*, WALL ST. J. (Mar. 18, 2018), <https://www.wsj.com/articles/trumps-opioid-battle-plan-includes-seeking-more-death-penalty-prosecutions-1521414347> [<https://perma.cc/D2JW-N3R6>].

<sup>44</sup> Scott Higham & Lenny Bernstein, *New Drug Law Makes It ‘Harder for Us to Do Our Jobs,’ Former DEA Officials Say*, WASH. POST (Dec. 15, 2017), [https://www.washingtonpost.com/graphics/2017/investigations/dea-law/?utm\\_term=.6cc2264b1f35](https://www.washingtonpost.com/graphics/2017/investigations/dea-law/?utm_term=.6cc2264b1f35) [<https://perma.cc/X8YA-XEXH>].

law.<sup>45</sup> The final version dramatically curtailed the DEA's enforcement powers: the agency now must demonstrate that a company's actions represent "a substantial likelihood of an immediate threat" before it can halt drug shipments, whereas previously it needed only to show that they posed an "imminent danger" to the community.<sup>46</sup> The law also allows companies to submit "corrective action plans" before they can be sanctioned by the DEA,<sup>47</sup> which one former DEA investigator called a "get out of jail free card[.]"<sup>48</sup>

More recently, the new two-year budget deal passed in early 2018 promised funding for the epidemic, the details of which were not specified.<sup>49</sup> Additionally, a bipartisan group of senators introduced a follow-up bill to 2016's Comprehensive Addiction and Recovery Act, commonly referred to as CARA 2.0.<sup>50</sup> A version of the bill was introduced in the House of Representatives by Tennessee Representative Marsha Blackburn.<sup>51</sup> If passed, CARA 2.0 would, among other things, commit more funding to the fight against the opioid crisis, restrict access to opioid painkillers, improve access for medication-assisted treatment, and increase civil and criminal penalties for opioid manufacturers if they fail to report suspicious orders or fail to prevent diversion.<sup>52</sup>

The impact of Eric's articles and its aftermath can be seen far beyond the nation's courtrooms and

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<sup>45</sup> *Id.*

<sup>46</sup> Ensuring Patient Access and Effective Drug Enforcement Act of 2016, Pub. L. No. 114-145, § 2(a)(1), 130 Stat. 354 (2016) (codified as amended at 21 U.S.C. § 823 (2017)).

<sup>47</sup> Ensuring Patient Access and Effective Drug Enforcement Act of 2016, Pub. L. No. 114-145, § 2(a)(2), 130 Stat. 354 (codified as amended at 21 U.S.C. § 824 (2016)).

<sup>48</sup> See Higham & Bernstein, *supra* note 44.

<sup>49</sup> See, e.g., Bipartisan Budget Act of 2018, H.R. 1892, 115th Cong. § 50723 (2018).

<sup>50</sup> CARA 2.0 Act of 2018, S. 2456, 115th Cong. (2018).

<sup>51</sup> CARA 2.0 Act of 2018, H.R. 5311, 115th Cong. (2018).

<sup>52</sup> *Id.*

legislatures, with some good results and some not as positive. Eric discussed some of these results at the symposium. For example, while he was relieved that many of the opioid “pill mills” in West Virginia had been shut down or had voluntarily closed their doors, he suspected that a number of them had simply changed the signs on their doors and morphed into “treatment centers” that use medication to treat the opioid addicts that they helped to create.

Medication-assisted treatment for opioid addiction is still very controversial.<sup>53</sup> The main criticism of using medication in this context is that it is just replacing one drug - whether an opioid painkiller or heroin - with another, such as methadone, buprenorphine, and naltrexone.<sup>54</sup> Research clearly demonstrates, however, that medication improves outcomes for patients with opioid use disorders.<sup>55</sup>

Along with the success of these treatments, several tag-along legal issues have arisen which are worthy of monitoring. One involves claims by the Attorneys General of 35 states and the District of Columbia that British pharmaceutical manufacturer Indivior Inc. and U.S. company MonoSol Rx “product hopped” in order to delay less expensive generic versions

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<sup>53</sup> See, e.g., Sameer Hassamal et al., *Overcoming Barriers to Initiating Medication-Assisted Treatment for Heroin Use Disorder in a General Medical Hospital: A Case Report and Narrative Literature Review*, J. PSYCHOL. PRAC. 221 (2017).

<sup>54</sup> *Medication and Counseling Treatment*, SUBSTANCE ABUSE & MENTAL HEALTH ADMIN. (APR. 8, 2018), <https://www.samhsa.gov/medication-assisted-treatment/treatment> [<https://perma.cc/5VC4-LULF>]. Buprenorphine (Subutex) and Buprenorphine-naloxone (Suboxone) were approved by the U.S. FDA in 2002 to treat opiate dependence. Naloxone is the drug used to revive overdose victims.

<sup>55</sup> Mollie Durkin, *Primary Care Takes on Opioid Addiction*, ACP INTERNIST: OPIOIDS (Oct. 2017), <https://acpinternist.org/archives/2017/10/primary-care-takes-on-opioid-addiction.htm> [<https://perma.cc/L49U-BM2H>].

of Suboxone, Indivior's opioid addiction treatment drug.<sup>56</sup> The defendants in that case are accused of conspiring to create a sublingual film version of its Suboxone drug shortly before its license expired in order to extend its patent; of incrementally increasing the price of its tablets and engaging in potentially misleading marketing to encourage patients and doctors to switch to the new film version; and of then announcing its intent to remove the tablets from the market entirely.<sup>57</sup>

Another pharmaceutical manufacturer in the ever-growing opioid treatment market has drawn fire for its marketing practices. Alkermes, a Massachusetts company, makes a monthly injectable treatment medication called Vivitrol that blocks the effects of opioids and reduces cravings, and the company has taken its aggressive marketing pitch directly to drug court judges, prosecutors, and other officials in the criminal justice system who appear receptive to the "nonaddictive" qualities of its product.<sup>58</sup> According to medical professionals, this approach is misleading and contributes to the "existing stigma on the use of opioid [methadone or buprenorphine] therapy in the treatment of opioid addiction, despite a large and robust evidence base showing [its] effectiveness . . . for opioid addiction."<sup>59</sup>

In addition to the potentially predatory practices of the companies and individuals seeking to exploit the market for opioid addiction treatment, there are other

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<sup>56</sup> See *Wisconsin v. Indivior Inc.*, Civ. No. 16-5073, 2017 WL 3967911 (E.D. Pa. Sept. 8, 2017).

<sup>57</sup> *Id.*

<sup>58</sup> See, e.g., Press Release, U.S. Senator Kamala Harris, Senator Harris Launches Investigation into Pharmaceutical Manufacturer Alkermes Regarding Opioid Addiction Treatment Manipulation (Nov. 6, 2017), <https://www.harris.senate.gov/news/press-releases/senator-harris-launches-investigation-into-pharmaceutical-manufacturer-alkermes-regarding-opioid-addiction-treatment-manipulation> [<https://perma.cc/G5C7-YFKP>].

<sup>59</sup> *Id.*

obvious downsides to the successful closure of many of the unethical pill mills that blighted our rural communities. Some of the poor souls who are no longer able to access opioid prescriptions have turned to heroin or to the very deadly synthetic opioid, fentanyl. According to the CDC, “illicitly manufactured fentanyl is now a major cause of opioid overdose deaths in multiple states.”<sup>60</sup> One law enforcement officer compared it to a community weapon of mass destruction: “[i]t’s manufactured death.”<sup>61</sup>

Hopefully, no one will be discouraged from seeking to combat the opioid crisis in all of its forms, whether the drug has been produced legally or illegally. We should look to Eric’s efforts, and those of our colleagues whose legal work supported him, for courage and inspiration. The unsealed data that Eric and Pat et al. secured in West Virginia are still among the only such data that are publicly-available. The industry, with support from the U.S. Department of Justice and the U.S. DEA, is still demanding that its data be protected on the grounds that disclosure could violate privacy rights, breach trade secrets, interfere with law enforcement investigations, and encourage criminal activity.<sup>62</sup> This is

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<sup>60</sup> Maggie Fox, *Synthetic Fentanyl Deaths Rise in Americans Opioid Epidemic*, NBC NEWS: HEALTH (Oct. 27, 2017), <https://www.nbcnews.com/storyline/americas-heroin-epidemic/synthetic-fentanyl-deaths-rise-americans-opioid-epidemic-n814956> [<https://perma.cc/S42J-CTEH>].

<sup>61</sup> Nicole Lewis et al., *Fentanyl Linked to Thousands of Urban Overdose Deaths*, WASH. POST: NAT’L (Aug. 17, 2017), [https://www.washingtonpost.com/graphics/2017/national/fentanyl-overdoses/?utm\\_term=.d64447b619c9](https://www.washingtonpost.com/graphics/2017/national/fentanyl-overdoses/?utm_term=.d64447b619c9) [<https://perma.cc/ZRV4-N57W>].

<sup>62</sup> Letter from David A. Sierleja, First Assistant U.S. Attorney, N. Dist. of Ohio, to Paul T. Ferrell, Jr., Partner, Green, Ketchum, Farrell, Bailey & Tweel LLP (Feb. 26, 2018), <https://images.law.com/contrib/content/uploads/documents/398/11419/Critical-Mass-opioid-DOJ-letter.pdf> [<https://perma.cc/EQ9L-FBGV>].

despite the Justice Department's request to participate in the settlement talks in the large MDL pending in the Northern District of Ohio.<sup>63</sup>

This reluctance is understandable. The publicly-available raw numbers in Tennessee are sobering. In Knox County alone, there were 294 suspected drug overdose deaths in 2017 and 84 so far in 2018. Those are not just numbers: those are our children, mothers, fathers, siblings, and friends, and each leaves behind grieving loved ones, all of whom deserve the best of our combined professional efforts. As painful as the truth may be, lawyers and journalists should be working to uncover it, individually and as partners. Eric and his legal support may be a tough, if not an impossible, act to follow, but it is one to which I hope that we all will aspire.

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<sup>63</sup> United States' Motion to Participate in Settlement Discussions and as Friend of the Court, *In re* National Prescription Opiate Litigation, MDL No. 1:17-MD-2804 (N.D. Ohio April 2, 2018). This apparent cognitive dissonance appears to be an issue amongst the manufacturing community, too. OxyContin manufacturer Purdue Pharma recently announced that it would stop promoting opioids to physicians, *see OxyContin Maker Purdue Pharma Stops Promoting Opioids, Cuts Sales Staff*, WASH. POST: HEALTH SCIENCE (Feb. 10, 2018), [https://www.washingtonpost.com/national/health-science/oxycontin-maker-purdue-pharma-to-stop-promoting-the-drug-to-doctors/2018/02/10/c59be118-0ea7-11e8-95a5-c396801049ef\\_story.html](https://www.washingtonpost.com/national/health-science/oxycontin-maker-purdue-pharma-to-stop-promoting-the-drug-to-doctors/2018/02/10/c59be118-0ea7-11e8-95a5-c396801049ef_story.html) [https://perma.cc/9FR5-4WSP], while at the same time “funneling \$4.7 million to organizations and physicians from 2012 through last year” that promoted the use of opioid painkillers. Associated Press, *Opioid Makers Gave \$10 Million to Drug Advocacy Groups Amid Epidemic*, NBC NEWS: NEWS (Feb. 18, 2018), <https://www.nbcnews.com/storyline/americas-heroin-epidemic/opioid-makers-gave-10m-advocacy-groups-amid-epidemic-n849211> [https://perma.cc/LW39-63UK].