

# Letters

## RESEARCH LETTER

### Characteristics and Scope of Training of Clinicians Participating in the US Direct-to-Consumer Marketplace for Unproven Stem Cell Interventions

More than 700 US clinics advertise unproven stem cell treatments.<sup>1</sup> Hematopoietic stem cell transplants to treat various hematologic disorders are evidence-based whereas most other stem cell interventions are investigational. This study examined the characteristics and scope of training of clinicians performing unproven stem cell procedures.

**Methods** | Through systematic internet searches and content analysis, a 2016 study identified 351 US companies marketing unproven stem cell procedures provided at 570 clinics. The largest concentrations of companies were in California, Florida, and Texas.<sup>2</sup> Focusing on companies in these 3 states and identified in the 2016 study,<sup>2</sup> we excluded companies that ceased marketing stem cell procedures by January 2018. From company websites, we extracted information related to characteristics and training of all identified professionals. For physicians, we examined state medical board licensing databases to confirm qualifications and compared information obtained from the Federation of State Medical Board (FSMB) Physician Data Center (PDC). The PDC contains specialty board certifications from the American Board of Medical Specialties (ABMS), whereas most information in state medical board databases is self-reported. When discrepancies were found, information from the PDC was used.

To determine scope of training, 2 coders with medical expertise (W.F. and J.F.) used their judgment to independently review conditions each company claimed to treat and determined whether at least 1 physician at the company had the appropriate residency or fellowship training required to treat such conditions. Given the prevalence of companies treating orthopedic indications with stem cells, we compared orthopedic with nonorthopedic facilities using a 2-sided  $\chi^2$  test calculated using JMP Pro14 (SAS Institute Inc), with a  $P < .05$  considered statistically significant. Companies were classified as orthopedic if they exclusively treated orthopedic conditions based on the *ABMS Guide to Medical Specialties*<sup>3</sup> and the judgment of both coders. Coders recognized that different specialists could treat the same conditions. Generalists were considered not to have specialty training to administer advanced stem cell procedures. Coders were in all cases able to reach agreement concerning company classification and scope of training.

**Results** | Of 183 identified companies, 166 continued to advertise in 2018. In total, 608 clinicians were identified, of whom 401 (66%) were physicians. Physician assistants, nurses, and complementary and alternative medicine practitioners were

Table 1. Professional Backgrounds of Physicians and Nonphysicians Providing Stem Cell Interventions in California, Florida, and Texas

Profession	Individuals, No. (%)
<b>Physicians</b>	
Doctor of medicine	338 (55.6)
Doctor of osteopathy	56 (9.2)
Medical degree (eg, MBBS) from non-US schools	7 (1.2)
Total physicians	401 (66.0) <sup>a</sup>
<b>Nonphysicians</b>	
Physician assistants	55 (9.0)
Nurses	34 (5.6)
Complementary and alternative medicine practitioners	32 (5.3)
Podiatrists	29 (4.8)
Physical therapists	18 (3.0)
Other <sup>b</sup>	13 (2.3)
Scientists with a master's degree or doctorate in philosophy	10 (1.6)
Unclear qualifications	10 (1.6)
Dentists	6 (1.0)
Total nonphysician clinicians	207 (34.0)
<b>Total clinicians</b>	<b>608 (100)</b>

<sup>a</sup> Mean age of 55 years (range, 32-97 years). Mean licensed years of practice of 25 years (range, 2-61 years).

<sup>b</sup> Includes respiratory therapists, estheticians, clinical laboratory technicians, athletic trainers, radiology practitioner assistants, and support staff.

the most common nonphysicians (Table 1). Five companies were staffed completely by podiatrists, 2 by naturopaths, 1 by dentists, and 1 by practitioners with unclear qualifications. Forty percent of companies were solo practices; 27% had 2 to 3 practitioners; 14%, 4 to 5 practitioners; and 19%, 6 or more practitioners.

Among the 401 physicians, 91.5% were male and 80.5% completed medical training in the United States. Physicians represented 20 different types of residencies, including orthopedics (30.8%), anesthesiology (15.9%), physical medicine and rehabilitation (10.8%), and family medicine (10.4%) (Table 2). Physicians completed training in 25 different fellowships, including orthopedics (28.5%), sports medicine (24.3%), and pain medicine (21.8%) (Table 2).

Of the 157 companies with a physician, 81 companies (52%) that advertised stem cell treatments had at least 1 physician with formal training matching the conditions claimed to treat. Among orthopedic-focused practices, 68 (77%) had 1 or more physicians with appropriate specialty training. Only 13 companies (19%) that marketed stem cells for nonorthopedic indications had physicians practicing within their scope of training ( $P < .001$ ).

**Table 2. Residency and Fellowship Training of Physicians Offering Stem Cell Interventions in California, Florida, and Texas**

Specialty	No. (%)	
	Residencies	Fellowships
Addiction medicine		2 (0.8)
Anesthesiology	66 (15.9)	2 (0.8)
Cardiology		5 (2.1)
Colon and rectal surgery		2 (0.8)
Cosmetic surgery		7 (2.9)
Critical care		2 (0.8)
Dermatology	5 (1.0)	
Emergency medicine	4 (1.0)	2 (0.8)
Family medicine	43 (10.4)	1 (0.4)
Gastroenterology		1 (0.4)
General surgery	20 (4.8)	4 (1.7)
Geriatrics		2 (0.8)
Internal medicine	25 (6.0)	
Interventional radiology		1 (0.4)
Neurological surgery	16 (3.9)	4 (1.7)
Neurology	3 (0.7)	1 (0.4)
Obstetrics and gynecology	6 (1.4)	1 (0.4)
Occupational medicine	1 (0.2)	1 (0.4)
Ophthalmology	1 (0.2)	
Orthopedics	128 (30.8)	68 (28.5)
Otolaryngology	11 (2.7)	2 (0.8)
Pain medicine <sup>a</sup>		52 (21.8)
Pathology	3 (0.7)	
Pediatrics	4 (1.0)	
Plastic surgery	20 (4.8)	7 (2.9)
Physical medicine and rehabilitation	45 (10.8)	6 (2.5)
Radiology	9 (2.2)	5 (2.1)
Rheumatology		1 (0.4)
Sleep medicine		2 (0.8)
Sports medicine <sup>b</sup>		58 (24.3)
Urology	4 (1.0)	
Vascular surgery	1 (0.2)	

<sup>a</sup> Pain medicine fellowships were primarily physicians trained in anesthesiology and physical medicine and rehabilitation.

<sup>b</sup> Sports medicine fellowships were primarily physicians trained in orthopedics and family medicine.

**Discussion** | Many clinicians provided stem cell interventions for conditions outside their scope of training. Unlicensed stem cell interventions pose risks.<sup>4</sup> Clinicians practicing beyond their scope of training could increase risks to patients.<sup>5</sup>

This study has several limitations. The analysis was limited to clinicians from 3 states and did not include clinicians who entered the marketplace after 2016. Assessing scope of training relied on coders' judgment based on residency and fellowship training and did not consider that some physicians may have additional training. Scope of training was underestimated because it was defined at the company level.

In 2018, the FSMB<sup>6</sup> reported that 17 of 51 boards investigated complaints, and 8 took disciplinary actions related to physicians' performing unlicensed stem cell procedures. State medical boards should consider investigating licensees sus-

pected of violating professional standards when providing unproven stem cell interventions, especially those advertising treatment outside their scope of training.

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1. Turner L. The US direct-to-consumer marketplace for autologous stem cell interventions. *Perspect Biol Med*. 2018;61(1):7-24. doi:10.1353/pbm.2018.0024
2. Turner L, Knoepfler P. Selling stem cells in the USA: assessing the direct-to-consumer industry. *Cell Stem Cell*. 2016;19(2):154-157. doi:10.1016/j.stem.2016.06.007
3. American Board of Medical Specialties. *ABMS Guide to Medical Specialties*. <https://www.abms.org/member-boards/specialty-subspecialty-certificates/>. Published 2019. Accessed April 5, 2019.
4. Bauer G, Elsallab M, Abou-El-Enein M. Concise review: a comprehensive analysis of reported adverse events in patients receiving unproven stem cell-based interventions. *Stem Cells Transl Med*. 2018;7(9):676-685. doi:10.1002/sctm.17-0282
5. Federation of State Medical Boards. Position statement on practice drift. <https://www.fsmb.org/siteassets/advocacy/policies/position-statement-on-practice-drift.pdf>. Published April 2016. Accessed March 23, 2019.
6. Federation of State Medical Boards. Regenerative and stem cell therapy practices: report and recommendations of the Workgroup to Study Regenerative and Stem Cell Therapy Practices. <http://www.fsmb.org/siteassets/advocacy/policies/fsmb-stem-cell-workgroup-report.pdf>. Published April 2018. Accessed March 23, 2019.