EXHIBIT

The Ohio Dental "Specialist" Survey

Saperstein Associates, Inc. | May 2018

Methodology

elephone interviews were conducted with 812 Ohio residents, 18 or ol
elected at random.

ollectively, the interviews focused on four areas of dentistry: dental
nplants, orthodontia, TMJ disorders, and oral surgery.

ach resident was queried on two of the areas, assigned randomly, usin
e following guide:

dental implants, then orthodontia (n = 66)
dental implants, then TMJ disorders (n = 63)
dental implants, then oral surgery (n = 70)
orthodontia, then dental implants (n = 69)
orthodontia, then TMJ disorders (n = 75)
orthodontia, then oral surgery (n = 60)
TMJ disorders, then dental implants (n = 66)
TMJ disorders, then orthodontia (n = 66)
TMJ disorders, then oral surgery (n = 67)
oral surgery, then dental implants (n = 75)
oral surgery, then orthodontia (n = 71)
oral surgery, then TMJ disorders (n = 64)

ne guide netted for each area at least 400 interviews:

Dental implants:	n = 410
Orthodontia:	n = 408
TMJ disorders:	n = 400
Oral surgery:	n = 407

ne interviews were conducted with adults on cell phones (95%) and la nes (5%).

ne Margin or Error, or MoE, for a random sample of 812 interviews is ± ercentage points at the 95 percent level of confidence. The comparab gure for a random sample of 400 interviews is ±4.9 percentage points.

ne data were weighted to more accurately reflect known population arameters.

The survey respondents represent Ohio's adult population on several dimensions, including gender, age, race, education, and housing.

	Actual*	Sample
der		
Male	48%	49%
Female	52%	51%
18 to 24	12%	11%
25 to 34	16%	14%
35 to 44	16%	15%
45 to 54	18%	21%
55 to 64	18%	18%
65 or older	20%	21%

	Actual*	Sar
Race		
Black	12%	1
White	82%	8
Other	6%	
Education		
< Bachelor's	75%	7
Bachelor's ≥	25%	2
Housing		
Own	66%	6
Rent	34%	3

12-2016 American Community Survey 5-Year Estimates and 2010 Census Summary File 1

The Questions

s I mentioned, this survey is about the dental profession here in Ohio.
o, first, have you, yourself, been to a dentist, for any reason, during th
ast two years?

- Yes
- No
- Don't know / Not sure

Was that a general dentist, a specialist, or have you been to both?

- General dentist only
- Specialist only
- Both
- Don't know / Not sure

nd, specifically, what kind of specialist was that? (open-ended)

a dentist in your community advertised as a specialist in _____,* wou
ou be inclined to think that he or she had completed an accredited
sidency program in _____,* in addition to dental school, or not?

- Yes
- No
- Don't know / Not sure

a dentist in your community advertised as a specialist in _____,* wou
ou be inclined to think that he or she was more qualified, less qualifie
r just as qualified as a general dentist who does _____?*

- More qualified
- Less qualified
- Just as qualified
- Don't know / Not sure

tal implants, orthodontia, TMJ disorders, oral surgery

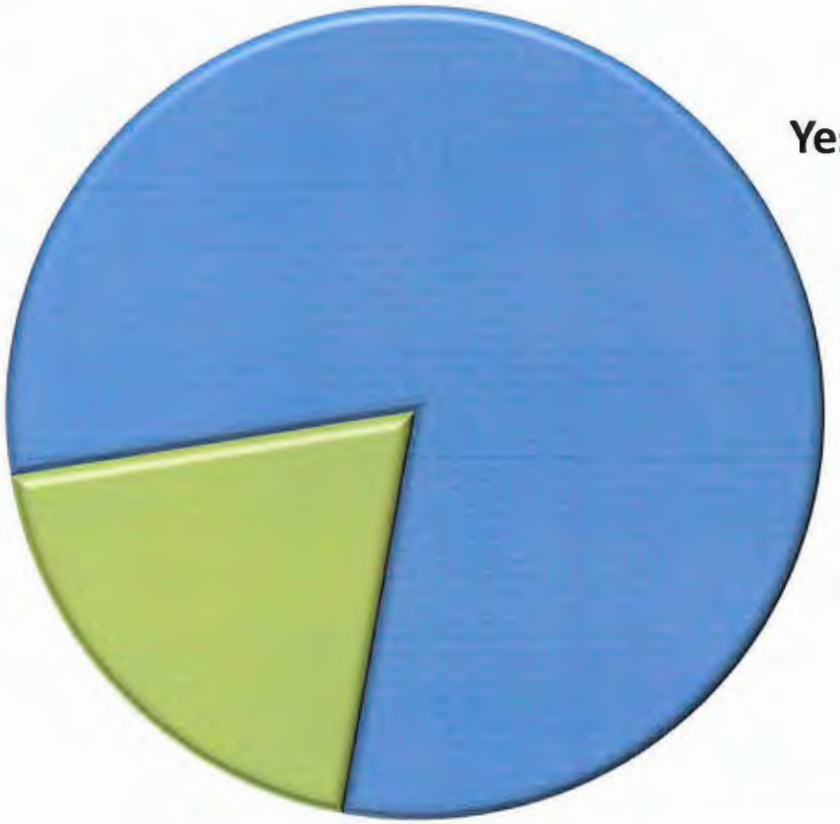
you learned that a dentist in your community who advertised as a ecialist in _____* had not completed an accredited residency progran _____,* would you be more likely or less likely to choose that dentist wouldn't that make a difference?

- More likely
- Less likely
- No difference
- Don't know / Not sure

tal implants, orthodontia, TMJ disorders, oral surgery

Summary of Findings

"... have you, yourself, been to a dentist, for any reason, during the past <u>two</u> years?"

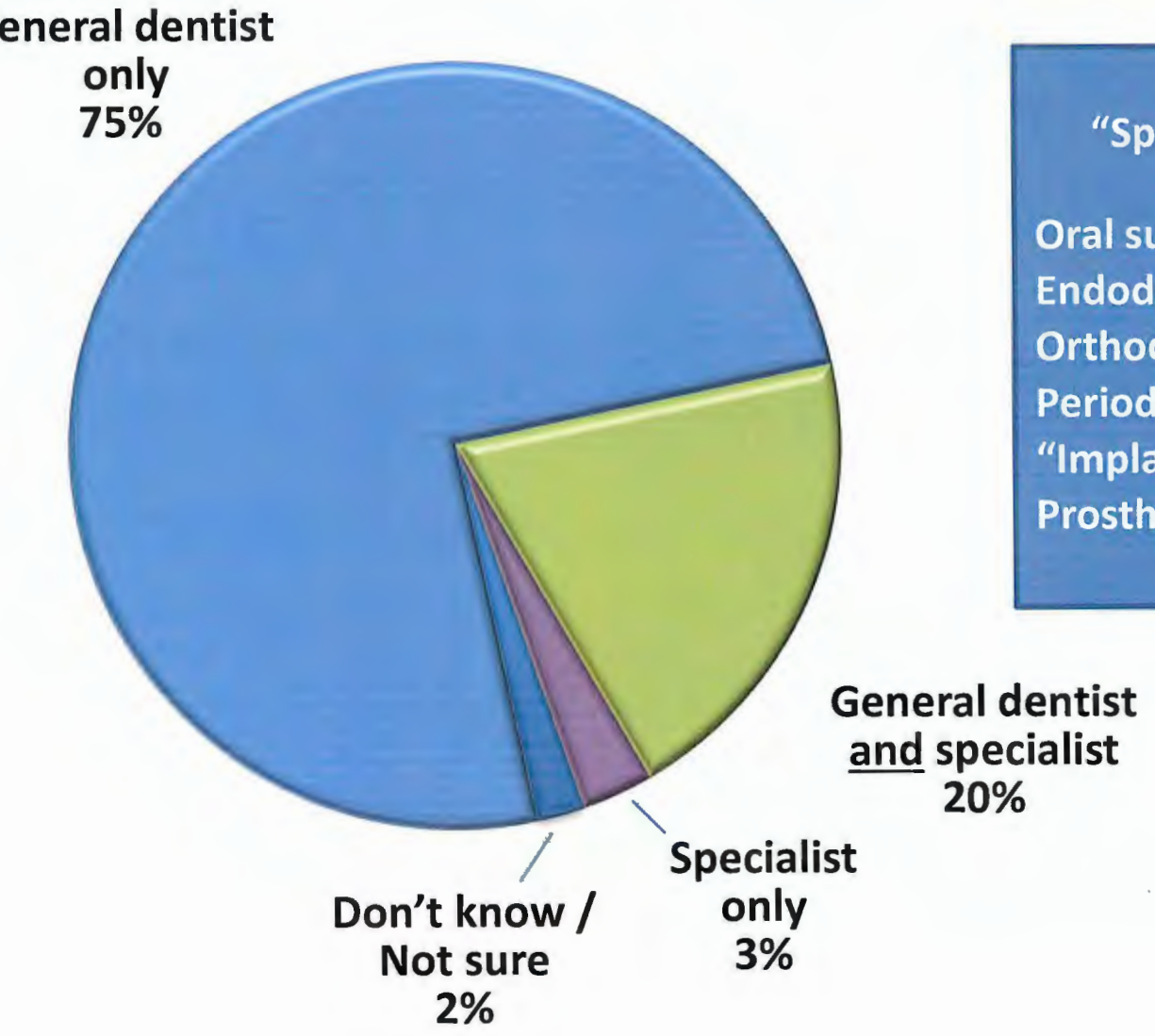


Yes, have been to a dentist 82%*

No, have not been to a dentist 18%

*The Kaiser Family Foundation reports in 2016, 68% of Ohio adults had been t dentist or dental clinic within the past year.

"Was that a general dentist, a specialist, or have you been to both?"



Most Common "Specialists" Mentioned

Oral surgeon
Endodontist ("root canal")
Orthodontist
Periodontist ("gums")
"Implantologist"
Prosthodontist ("crown")

		Dental Implants (n=410)	Orthodontia (n=408)	TMJ Disorders (n=400)	S (n
ntist in your community advertised as a ist in _____, would you be inclined to hat he or she had **completed an accred-sidency program** in _____, in addition to school, or not?	**Yes**	**78%**	**88%**	**73%**	
	No	14%	8%	15%	
	DK	8%	4%	12%	
ntist in your community advertised as a ist in _____, would you be inclined to hat he or she was more **qualified**, less ed, or just as qualified as a general den-o does _____?	**More**	**68%**	**70%**	**65%**	
	Less	5%	6%	4%	
	Just as	23%	21%	26%	
	DK	4%	3%	5%	
earned that a dentist in your community dvertised as a specialist in _____ had not eted an accredited residency program in would you be more likely or less likely to that dentist, or wouldn't that make a nce?	More	5%	5%	5%	
	Less	**79%**	**81%**	**70%**	
	No dif	15%	13%	23%	
	DK	1%	1%	2%	

Appendix

The Dental "Specialist" Survey

(n = 812)*

Land Line Sample

A. Hello. My name is _____ _____. I'm calling from Saperstein Associates, an independent opinion research firm in Columbus. We are conducting a short survey about the dental profession here in Ohio – and your household has been randomly selected to participate. This is not a sales call; we are interested only in the opinions of the people we interview.

B. (OPEN QUOTAS) To make this survey scientific, I need to speak with the adult in your household, 18 or older, who is having the next birthday. Is that you or someone else?

--	Me	(SKIP TO E)
--	Someone else	(GO TO C)
--	Don't know / Not sure / Refused	(TERMINATE)

(NEED MEN, MAN ON PHONE) To make this survey scientific, I need to speak with the man in your household, 18 or older, who is having the next birthday. Is that you or someone else?

--	Me	(SKIP TO E)
--	Someone else	(GO TO C)
--	Don't know / Not sure / Refused	(TERMINATE)

(NEED MEN, WOMAN ON PHONE) To make this survey scientific, we need to speak with an equal number of men and women. In your household we need to speak with the man, 18 or older, who is having the next birthday.

C. May I speak with (him / her), please?

(IF RESPONDENT IS AVAILABLE, RETURN TO A)
(IF RESPONDENT IS NOT AVAILABLE, OBTAIN CALLBACK INFORMATION)

Cell Phone Sample

D. Hello. My name is _____ _____. I'm calling from Saperstein Associates, an independent opinion research firm in Columbus. We are conducting a short survey about the dental profession here in Ohio – and your phone number has been randomly selected to participate. This is not a sales call; we are interested only in the opinions of the people we interview.

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*Data were weighted to better reflect known population parameters
SOURCE: Saperstein Associates, Inc., March 2018. 18008

All Respondents

E. Is this a convenient time to ask you some questions? This takes about five minutes.

100%	Convenient	(GO TO F)
--	No	(SCHEDULE CALLBACK / TERMINATE)
--	Don't know / Not sure / Refused	(SCHEDULE CALLBACK / TERMINATE)

F. Thank you. Now, before I begin, I need to ask you this: Are you a resident of Ohio, 18 or older?

100%	Yes (Ohio resident and 18 or older)	(ASK G ONLY IF M/F QUOTA FILLED)
--	No	(TERMINATE)
--	Don't know / Not sure / Refused	(TERMINATE)

G. This next question I am required to ask, even though I know the answer: Are you male of female?

(IF QUOTA FILLED) I'm sorry. We have filled our quota for (women / men), which means that our last few interviews must be with (men / women) But, thank you anyway. (TERMINATE)

Section 1 / All Respondents

1. As I mentioned, this survey is about the dental profession here in Ohio. So, first, have you, yourself, been to a dentist, for any reason, during th past two years?

82%	Yes	(GO TO 2)
18%	No	(SKIP TO APPROPRIATE BATTERY)
0%	Don't know / Not sure	(SKIP TO APPROPRIATE BATTERY)
0%	Refused	(SKIP TO APPROPRIATE BATTERY)

2. Was that a general dentist, a specialist, or have you been to both? (n = 662)

75%	General dentist only	(SKIP TO APPROPRIATE BATTERY)
3%	Specialist only	(GO TO 3)
20%	Both	(GO TO 3)
2%	Don't know / Not sure	(SKIP TO APPROPRIATE BATTERY)
0%	Refused	(SKIP TO APPROPRIATE BATTERY

3. And, specifically, what kind of specialist was that? (n = 152)

22%	Oral surgeon
16%	Orthodontist
12%	Root canal
7%	Endodontist
7%	Extraction
5%	Implants
5%	Orofacial
5%	Periodontist
4%	Dentures
3%	Gum cleaning
3%	Wisdom teeth removal
2%	Crown specialist
2%	Prosthodontics
1%	Cosmetic
1%	Install prongs
1%	Maxillofacial surgeon
1%	Oral hygienist
1%	TMJ
1%	Tooth transplant
8%	Don't know / not sure
1%	Refused

ASK:

BATTERY 1, THEN BATTERY 2
BATTERY 1, THEN BATTERY 3
BATTERY 1, THEN BATTERY 4
BATTERY 2, THEN BATTERY 1
BATTERY 2, THEN BATTERY 3
BATTERY 2, THEN BATTERY 4
BATTERY 3, THEN BATTERY 1
BATTERY 3, THEN BATTERY 2
BATTERY 3, THEN BATTERY 4
BATTERY 4, THEN BATTERY 1
BATTERY 4, THEN BATTERY 2
BATTERY 4, THEN BATTERY 3

Battery 1: Dental Implants (n = 410)

4. These next few questions focus on dental implants, which, as you probably know, are artificial teeth surgically anchored to a patient's jaw where natural teeth are missing.

   Now, if a dentist in your community advertised as a specialist in dental implants, would you be inclined to think that he or she had completed an accredited residency program in dental implantology, in addition to dental school, or not?

   78% Yes
   14% No
   8% Don't know / Not sure
   0% Refused

5. If a dentist in your community advertised as a specialist in dental implants, would you be inclined to think that he or she was more qualified, less qualified, or just as qualified as a general dentist who does dental implants?

   68% More qualified
   5% Less qualified
   23% Just as qualified
   4% Don't know / Not sure
   0% Refused

6. Imagine for a moment that you needed a dental implant. If you learned that a dentist in your community who advertised as a specialist in dental implants had not completed an accredited residency program in dental implantology, would you be more likely or less likely to choose that dentist or wouldn't it make a difference?

   5% More likely
   79% Less likely
   15% No difference
   1% Don't know / Not sure
   0% Refused

Battery 2 / Orthodontia (n = 408)

7. These next few questions focus on orthodontics, which, as you probably know, often involves the treatment of crooked or misaligned teeth using braces or removable retainers.

   Now, if a dentist in your community advertised as a specialist in orthodontics, would you be inclined to think that he or she had completed an accredited residency program in orthodontics, in addition to dental school, or not?

   88% Yes
   8% No
   4% Don't know / Not sure
   0% Refused

8. If a dentist in your community advertised as a specialist in orthodontics, would you be inclined to think that he or she was more qualified, less qualified, or just as qualified as a general dentist who does orthodontics?

   70% More qualified
   6% Less qualified
   21% Just as qualified
   3% Don't know / Not sure
   0% Refused

9. Imagine for a moment that you, or someone else in your household, needed braces. If you learned that a dentist in your community who advertised as a specialist in orthodontics had not completed an accredited residency program in orthodontics, would you be more likely or less likely to choose that dentist, or wouldn't it make a difference?

   5% More likely
   81% Less likely
   13% No difference
   1% Don't know / Not sure
   0% Refused

Battery 3 / Orofacial Pain Management (n = 400)

10. These next few questions focus on TMJ disorders, which, as you probably know, can cause pain in your jaw joint and in the muscles that contro how your jaw moves.

    Now, if a dentist in your community advertised as a specialist in TMJ disorders, would you be inclined to think that he or she had completed ar accredited residency program in TMJ disorders and orofacial pain management, in addition to dental school, or not?

    73% Yes
    15% No
    12% Don't know / Not sure
    0% Refused

11. If a dentist in your community advertised as a specialist in TMJ disorders, would you be inclined to think that he or she was more qualified, less qualified, or just as qualified as a general dentist who treats TMJ disorders?

    65% More qualified
    4% Less qualified
    26% Just as qualified
    5% Don't know / Not sure
    0% Refused

12. Imagine for a moment that you were experiencing jaw pain. If you learned that a dentist in your community who advertised as a specialist in TM disorders had not completed an accredited residency program in TMJ disorders and orofacial pain management, would you be more likely or less likely to choose that dentist, or wouldn't it make a difference?

    5% More likely
    70% Less likely
    23% No difference
    2% Don't know / Not sure
    <1% Refused

Battery 4 / Oral Surgery (n = 407)

13. These next few questions focus on oral surgery, which, as you probably know, involves surgical dental procedures, including the removal o wisdom teeth.

    Now, if a dentist in your community advertised as a specialist in oral surgery, would you be inclined to think that he or she had completed a accredited residency program in oral surgery, in addition to dental school, or not?

    90% Yes
    5% No
    5% Don't know / Not sure
    0% Refused

14. If a dentist in your community advertised as a specialist in oral surgery, would you be inclined to think that he or she was more qualified, less qualified, or just as qualified as a general dentist who does oral surgery?

    68% More qualified
    5% Less qualified
    24% Just as qualified
    3% Don't know / Not sure
    0% Refused

15. Imagine for a moment that you, or someone else in your household, needed wisdom teeth removed. If you learned that a dentist in you community who advertised as a specialist in oral surgery had not completed an accredited residency program in oral surgery, would you be more likely or less likely to choose that dentist, or wouldn't it make a difference?

    5% More likely
    79% Less likely
    15% No difference
    1% Don't know / Not sure
    0% Refused

All Respondents

16. Finally, a few questions about you. First, in what Ohio county do you live? (n = 797)

    34% ODA District 1
    66% ODA District 2

    (See page 32 for detailed county frequency)

17. Do you own or rent your home? (n = 807)

    67% Own
    32% Rent
     1% Other

18. Which of the following best reflects the highest level of formal education you have completed: a high school diploma; an associate degree o certificate from a two-year college or trade school; a bachelor's degree from a four-year college or university; or a post-graduate degree, such as a master's, doctorate, medical, or law degree? (n = 812)

    40% A high school diploma (or less)
    31% An associate degree or certificate from a two-year college or trade school
    18% A bachelor's degree from a four-year college or university
    11% A post-graduate degree, such as a master's, doctorate, medical, or law degree

19. Are you 18 to 24, 25 to 34, 35 to 44, 45 to 54, 55 to 64, 65 to 74, or 75 or older? (n = 812)

    11% 18 to 24
    14% 25 to 34
    15% 35 to 44
    21% 45 to 54
    18% 55 to 64
    15% 65 to 74
     6% 75 or older

20. And, finally, do you consider yourself White, Black or African-American, Hispanic, Asian, or something else? (n = 773)

84% White
10% Black or African-American
1% Hispanic
3% Asian
1% More than one race
1% Native American

21. That was my last question. Thank you for participating in this research. Good-bye. (TERMINATE)

22. GENDER:

49% Male
51% Female

EXHIBIT 2 tabbies

The South Dakota Dental "Specialist" Survey

Saperstein Associates, Inc. / December 2022

This research examines among adult residents of South Dakota the impact of the designation "specialist" on perceptions of dentists who include the word in ads promoting their services.

Methodology

online questionnaire was completed by 400 adult* residents of South Da
er a five-day period, beginning on October 14, 2022.

e participating residents were drawn from a panel created and manage
nata, an online panel provider (see: www.dynata.com/panel-book).

e margin of error for a random sample of 400 residents is ≤±4.9 percen
ints at the 95 percent level of confidence.

ta collected for this survey were weighted to more accurately reflect kn
pulation parameters.

deed, as the tables on the following slide illustrate, the survey respond
present South Dakota's adult population on several important demograp
cluding gender, age, race, education, and housing.

ned as 18 or older.

South Dakota Demographics: Actual v. Survey

	Actual*	Sample
Male	51%	51%
Female	49%	49%
18 to 24	14%	14%
25 to 34	16%	16%
35 to 44	21%	21%
45 to 54	18%	18%
55 to 64	11%	11%
65 to 74	10%	10%
75 or older	10%	10%

	Actual*	Sample
White	81%	81%
Native American	9%	9%
Hispanic	5%	5%
Black/African-Amer.	2%	2%
Other (including Asian)	3%	3%
Less than bachelor's	76%	76%
Bachelor's degree +	24%	24%
Homeowner	68%	68%
Other	32%	32%

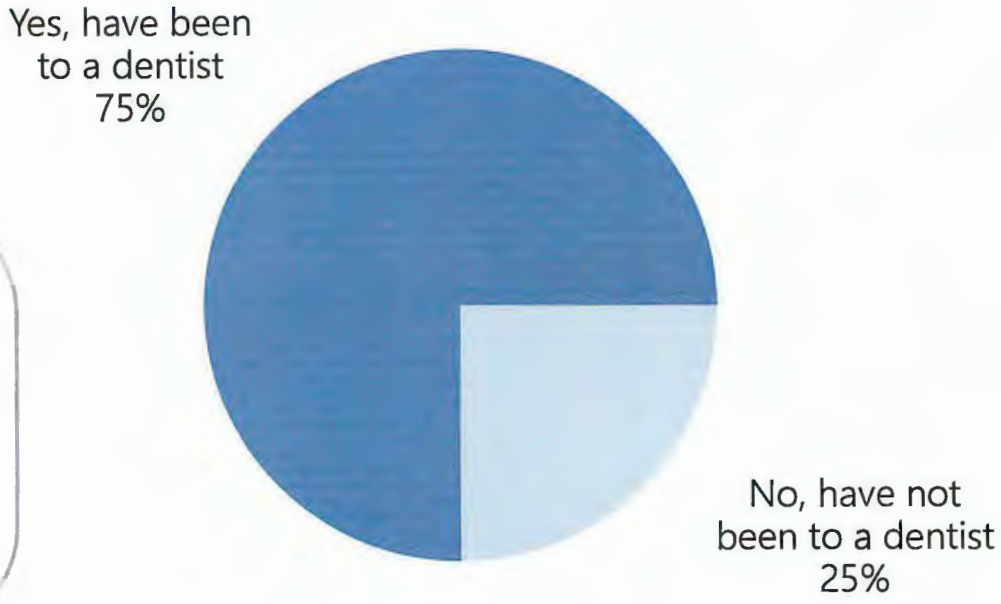
nfoplease.com, SD Demographic Statistics, 2000 / American Community Survey, South Dakota, U.S. Census, 2021 / U.S. Census, QuickFacts, South Dakota, 2021

ree dental specialties are addressed in this study: orthodontics, d
plants, and oral surgery. To minimize the time required to complete
line questionnaire, each participating resident addressed only two specia
ected at random and presented in a randomized order.

timately, 271 of the 400 participating residents responded to questions in
g orthodontics, 270 responded to questions involving dental implants,
9 responded to questions involving oral surgery.

Summary of Findings

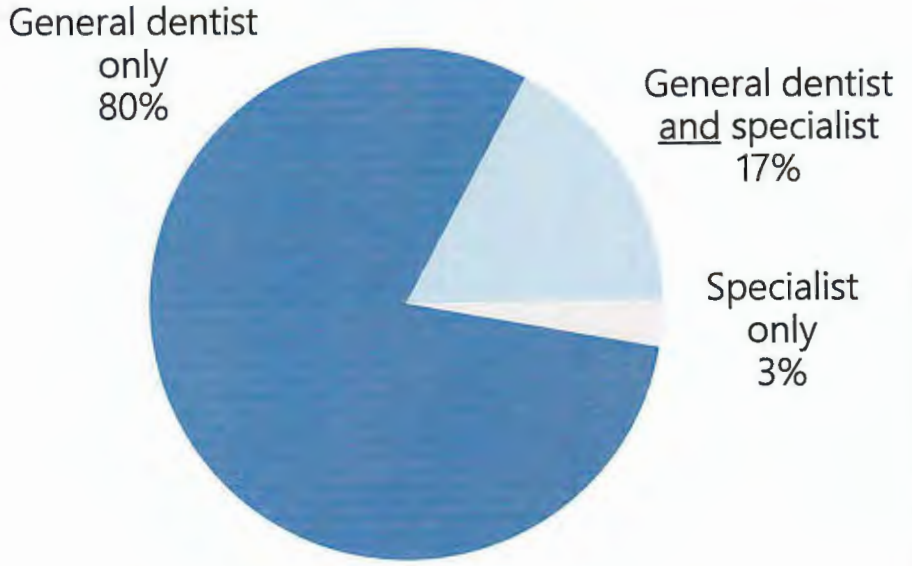
ve you, yourself, been to a dentist, for any reason, during the past two ye



The Kaiser Family Foundation reports that in 2020, 72% of South Dakota adults reported visiting a dentist or dental clinic within the past year.*

ww.kff.org / "Adults Who Report Visiting the Dentist or Dental Clinic within the Past Year," 2020

"Was that a general dentist, a specialist, or have you been to both?"



Most Comm
Specialists Ment
Oral surgeo
Orthodonti
Endodontis
Implantolog
Periodontis

The Key Questions

		Orthodontics (n=271)	Implants (n=270)	Oral S
ntist in your community advertised as a list in ____, would you be inclined to think e or she had completed an accredited ncy program in ____, in addition to dental , or not?	**Yes** No DK			
ntist in your community advertised as a list in ____, would you be inclined to think e or she was more qualified, less qualified, or qualified as a general dentist who does ____?	**More** Less Just as DK			
learned that a dentist in your community who ised as a specialist in ____ had not completed redited residency program in ____, would you re likely or less likely to choose that dentist, or n't it make a difference?	More **Less** No diff DK			

The Data

		Orthodontics (n=271*)	Implants (n=270)	Oral S (n=
ntist in your community advertised as a list in ____, would you be inclined to think e or she had completed an accredited ncy program in ____, in addition to dental , or not?	**Yes**	**82%**	**79%**	**8**
	No	8%	11%	
	DK	10%	10%	
ntist in your community advertised as a list in ____, would you be inclined to think e or she was more qualified, less qualified, or qualified as a general dentist who does ____?	**More**	**69%**	**72%**	**7**
	Less	4%	4%	
	Just as	20%	15%	1
	DK	7%	9%	
learned that a dentist in your community who ised as a specialist in ____ had not completed redited residency program in ____, would you re likely or less likely to choose that dentist, or n't it make a difference?	More	20%	23%	1
	Less	**64%**	**58%**	**6**
	No diff	8%	9%	
	DK	8%	10%	

ror for orthodontics and implants is ≤±5.9 pp. Sampling error for oral surgery is ≤±6.1 pp – all at the 95 percent level of confidence.

The Data

short, the survey reveals that at least seven out of ten adult residents of S
kota would be inclined to think that a dentist who advertises as a specia
thodontics, dental implants, or oral surgery ...

... had completed an accredited residency program in that specialt
addition to dental school, and ...

... was more qualified than general dentists who practice in those areas

oreover, a majority of these residents would be less inclined to choo
entist who advertises as a specialist in orthodontics, dental implants, or
rgery were they to learn that such a dentist had not completed an accre
sidency program in the relevant area.

Appendix

The South Dakota Dental "Specialist" Survey

(n = 400)*

come!

k you for participating in this research!

opinions are very important.

w Questions About You

Are you a resident of South Dakota?

100% Yes (GO TO 2)

Do you own or rent your home?

68% Own
29% Rent
3% Other: [text box]

Which of the following reflects the highest level of formal education you have completed?

4% Grade school
42% A high school diploma
29% An associate degree or certificate from a two-year college or trade school
15% A bachelor's degree from a four-year college or university
9% A post-graduate degree, such as a master's, doctorate, medical, or law degree
1% Other: [text box]

eighted to better reflect known population parameters / SOURCE: Saperstein Associates, Inc., October 2022, 22022

w Questions About You (cont'd)

Which of the following includes your age?

14%	18 to 24	(GO TO 5)
16%	25 to 34	(GO TO 5)
21%	35 to 44	(GO TO 5)
18%	45 to 54	(GO TO 5)
11%	55 to 64	(GO TO 5)
10%	65 to 74	(GO TO 5)
10%	75 or older	(GO TO 5)

Which of the following describes your gender?

51%	Male
49%	Female

Which of following describes your race or ethnicity?

81%	White or Caucasian
2%	Black or African-American
9%	Native American
5%	Hispanic
2%	Asian
1%	Other: [text box]

eighted to better reflect known population parameters / SOURCE: Saperstein Associates, Inc., October 2022, 22022

Dental Profession

survey deals with the dental profession.

Have you, yourself, been to a dentist, for any reason, during the past two years?

75%	Yes	(GO TO 8)
25%	No	(SKIP TO RANDOMIZED BATTERY)
<1%	Not sure	(SKIP TO RANDOMIZED BATTERY)

Was that a general dentist, a specialist, or have you been to both? (n = 300)

80%	General dentist only	(SKIP TO RANDOMIZED BATTERY)
3%	Specialist only	(GO TO 9)
17%	Both	(GO TO 9)
<1%	Not sure	(SKIP TO RANDOMIZED BATTERY)

Specifically, what kind of specialist was that? (n = 60) (MULTIPLE RESPONSES PERMITTED)

27%	Endodontist
60%	Oral surgeon
41%	Orthodontist
18%	Periodontist
19%	Implantologist
1%	Other: [text box]
7%	Not sure

TO RANDOMIZED BATTERY)

---

eighted to better reflect known population parameters / SOURCE: Saperstein Associates, Inc., October 2022, 22022

tal Implants (n=270 per question)

ollowing three questions focus on DENTAL IMPLANTS, which, as you may know, are artificial teeth surgically anchored to a patient's ja al teeth are missing.

If a dentist in your community advertised as a specialist in DENTAL IMPLANTS, would you be inclined to think that he or she had com accredited residency program in dental implantology, in addition to dental school, or not?

79% Yes
11% No
10% Not sure

If a dentist in your community advertised as a specialist in DENTAL IMPLANTS, would you be inclined to think that he or she was more less qualified, or just as qualified as a general dentist who does dental implants?

72% More qualified
4% Less qualified
15% Just as qualified
9% Not sure

Imagine for a moment that you needed a dental implant. If you learned that a dentist in your community who advertised as a sp DENTAL IMPLANTS had not completed an accredited residency program in dental implantology, would you be more likely or less likely that dentist, or wouldn't it make a difference?

23% More likely
58% Less likely
9% No difference
10% Not sure

eighted to better reflect known population parameters / SOURCE: Saperstein Associates, Inc., October 2022, 22022

odontics (n=271 per question)

ollowing three questions focus on ORTHODONTICS, which, as you may know, often involves the treatment of crooked or misaligned t
s or removable retainers.

If a dentist in your community advertised as a specialist in ORTHODONTICS, would you be inclined to think that he or she had cor
accredited residency program in orthodontics, in addition to dental school, or not?

82% Yes
8% No
10% Not sure

If a dentist in your community advertised as a specialist in ORTHODONTICS, would you be inclined to think that he or she was mor
less qualified, or just as qualified as a general dentist who does orthodontics?

69% More qualified
4% Less qualified
20% Just as qualified
7% Not sure

Imagine for a moment that, or someone else in your household, needed braces. If you learned that a dentist in your community who
as a specialist in ORTHODONTICS had not completed an accredited residency program in orthodontics, would you be more likely or le
choose that dentist, or wouldn't it make a difference?

20% More likely
64% Less likely
8% No difference
8% Not sure

***Surgery** (n=259 per question)*

ollowing three questions focus on ORAL SURGERY, which, as you may know, involves surgical dental procedures, including the removal
.

If a dentist in your community advertised as a specialist in ORAL SURGERY, would you be inclined to think that he or she had con
accredited residency program in oral surgery, in addition to dental school, or not?

84% Yes
9% No
7% Not sure

If a dentist in your community advertised as a specialist in ORAL SURGERY, would you be inclined to think that he or she was more qua
qualified, or just as qualified as a general dentist who does oral surgery?

74% More qualified
7% Less qualified
13% Just as qualified
6% Not sure

Imagine for a moment that, or someone else in your household, needed wisdom teeth removed. If you learned that a dent
community who advertised as a specialist in ORAL SURGERY had not completed an accredited residency program in oral surgery, wo
more likely or less likely to choose that dentist, or wouldn't it make a difference?

18% More likely
68% Less likely
8% No difference
6% Not sure

---

k You!

k you for participating in this research. Please click on "Submit" (or the forward arrow on your cell phone) to record your responses. S

eighted to better reflect known population parameters / SOURCE: Saperstein Associates, Inc., October 2022, 22022

This study was conducted by
Saperstein Associates
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Columbus, Ohio 43220
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1539 Heritage Lane
York, PA 17403

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PUBLISHED WORKS

"Trends in FDA Adverse Events Reporting for Inferior Vena Cava Filters and Estimated Insertions in the US, 2016 to 2020", co-author
JAMA Internal Medicine, January 23, 2023
https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2800829

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Circulation: Cardiovascular Quality and Outcomes, October 2022
Circ Cardiovasc Qual Outcomes. 2022;15:e009116. DOI: 10.1161/CIRCOUTCOMES.122.009116

"Assessing adverse event reports of hysteroscopic sterilization device removal using natural language processing", co-author
Pharmacoepidemiology & Drug Safety, December 1, 2021
https://onlinelibrary.wiley.com/doi/10.1002/pds.5402

"Is the FDA Failing Women?" co-author
AMA Journal of Ethics, September, 2021
https://journalofethics.ama-assn.org/article/fda-failing-women/2021-09

"Reporting of Death in US Food and Drug Administration Medical Device Adverse Event Reports in Categories Other Than Death", co-author
JAMA Internal Medicine, July 26, 2021
https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2782344?resultClick=1

"Medical Device Tracking—How it is and How it Should be", co-author
JAMA Internal Medicine, December 16, 2020
https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2774431

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JAMA Internal Medicine, September 28, 2020
https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2771088

"Miscategorization of Deaths in the US Food and Drug Administration Adverse Events Database", co-author
JAMA Internal Medicine, October 7, 2019
https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2752362

"Leading the Call for Reform of Medical Device Safety Surveillance", expert contributor
JAMA Internal Medicine, December 20, 2019
https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2757526?resultClick=1

"Unique device identifiers for coronary stent postmarket surveillance and research: A report from the Food and Drug Administration Medical Device Epidemiology Network Unique Device Identifier Demonstration", co-author
American Heart Journal, October 2014, Volume 168, Issue 4, Pages 405–413.e2
http://www.ahjonline.com/article/S0002-8703(14)00405-0/fulltext

"*Essureal Journey: Concepts, Concerns and Considerations for Hysteroscopic Sterilization*", edited by E. Scott Sills, MD, PhD, Nova Science Publishers, 2017, Chapter 5 by Madris Tomes, MBA

"*Unique Device Identification (UDI): 10 Things You Need to Know*", September 2014, author
http://avalere.com/expertise/life-sciences/insights/unique-device-identification-udi-10-things-you-need-to-know

"*Don't Hold Back on UDI Compliance*", QMed, August 17, 2016, co-author
https://www.mddionline.com/packaging/dont-hold-back-udi-compliance

"*Safety and Efficacy of Hysteroscopic Sterilization compared with Laparoscopic Sterilization: an Observational Cohort Study*", BMJ, October 13, 2015, expert contributor
https://www.bmj.com/content/351/bmj.h5162.full.print

Submitted for Publication: "*Data Sources and Applied Methods for Paclitaxel Safety Signal Discernment*", Therapeutic Innovation and Regulatory Science, co-author with director of FDA's Office of Epidemiology, and leading researchers at Cornell University, the University of Arkansas and Harvard Medical School.

EDUCATION AND PROFESSIONAL ACTIVITIES

MBA, IT Concentration – American University, Washington DC
BS Marketing, Minor in Insurance – Penn State University, University Park, PA
Project Management Professional (PMP) Certification – Project Management Institute
FDA MDEpiNET UDI Think Tank – Led scope and strategy workgroup for Duke Clinical Research Institute
AHRMM Learning UDI Community (LUC) – Advisor to American Hospital Association's LUC to improve hospital best practices of reporting adverse events directly to the FDA
FDA MDEpiNET – Member, Signal Discernment Analytics and Biostatistics Workgroup
American Hospital Association (AHA) – Member, Recall LUC Workgroup
Medical Device Innovation Consortium (MDIC) – Member Advisor, Science of Patient Input
Patient Safety Action Network, Member of Medical Device Roundtable

PROFESSIONAL EXPERIENCE

Device Events **July 2015 – Present**
CEO

Ms. Kinard founded, developed and launched Device Events, a medical device surveillance system that uses natural language processing to provide clear and comprehensive metrics and reports on the millions of medical device adverse event reports (MDRs) submitted to the FDA. She is an active participant in the UDI Think Tank and the MDEpiNet (FDA's medical device epidemiology network) public private partnership for post-market surveillance. She leads the work group of health payers and regulators in order to determine the UDI business rules for managing devices through the continuum of care.

- Biostatistics work group on Silicone Gel Bleed, November 2021 - present

- Member of the Medical Device Innovation Consortium's (MDIC) Patient Engagement Panel to advise FDA and other stakeholders of better ways to communicate device information to patients and care providers. Convened on April 21, 2022.
- Recommended for the FDA Orthopedic Devices Advisory Committee by the Patient Safety Action Network. Accepted (May 2022) by FDA lead scientist and awaiting first panel meeting.
- The Director of Epidemiology at the FDA's Center for Medical Devices and Radiological Health recommended Ms. Kinard lead the adverse event reporting data recommendations for the FDA MDEpiNet Signal Discernment, Analytics and Biostatistics Working Group, September 2019 – 2020.
- The FDA recommended Ms. Kinard to lead the AHA (American Hospital Association) workgroup to develop best practices to integrate UDI in Adverse Events reporting for hospitals as well as to encourage the direct reporting of adverse events by physicians directly to the FDA. Future state process flows for hospitals were adopted and presented in August, 2017.
- Informal Advisor to the Department of Homeland Security, HHS Office of the Inspector General and Senator Richard Durbin's office.

Avalere Health **April 2014 – July 2015**
Senior Manager, Business Intelligence

Ms. Kinard conceptualized and created a medical device post-market surveillance product for the Life Sciences sector. She also provided domain expertise and thought leadership in the UDI space to provide enhanced adverse event reporting analytics, improve patient safety and inform enforcement activities for medical device companies, government agencies and health plans/payers.

Ms. Kinard educated regulators and pushed forward the initiative to incorporate UDI into claims to improve patient outcomes, reduce fraud and standardize the reporting mechanisms for all UDI formats. She continues her work in this area by advising regulatory agencies on next steps after Congressional approval.

Food and Drug Administration **2012 – 2014**
Public Health Analyst (GS-14)

FDA/Center for Devices and Radiological Health (CDRH)/Office of Surveillance and Biometrics (OSB)/Division of Post-market Surveillance (DPS)

As the FDA's Adverse Events Reporting System (FAERS) Manager, Ms. Kinard provided domain expertise and project leadership to provide for enhanced adverse event report review and analytics, and to incorporate the UDI into medical device reporting efforts. Assisted in development of the Medwatch (3500) Form instructions. Trained in every aspect of adverse event reporting (intake, modifications, coding, redaction, and regulatory requirements). Developed Additional Information (AI) letters to the manufacturer, and mapped the ASR implementation business rules for the MAUDE-replacement system.

As the UDI (Unique Device Identification) External Program Manager, Ms. Kinard furthered UDI outreach in clinical and hospital settings, in patient and consumer settings, and in regulatory spaces through program oversight of:

- ASTER-D – managed a project for spontaneous triggering of adverse events through patient outcomes reported in Electronic Health Records (Outcome Sciences, Epic and Quantros).
- Brookings Institute – drove the potential adoption of UDI through regulatory channels such as Meaningful Use and HIPAA via Brookings panels designed to educate and inform the UDI Implementation Plan.
- Cardiac Stent Demonstration Project – oversight of UDI component of project with Harvard University and Mercy Health System.

- Hip and Knee Replacement Demonstration Project – oversight of UDI component of project with Cornell University and Kaiser Permanente.
- Medwatch – attended meetings on behalf of CDRH to make recommended changes to the Medwatch (3500) form.
- eMDR – attended meeting to discuss how eMDR and MAUDE would change (business rules and system specifications) after pending regulation changes.

Led meetings with the UK's Medicines and Healthcare Devices Regulatory Agency (MHRA) to discuss the technical and regulatory implications of sharing GUDID data on a global basis. This included communication of a potential timeline for the GUDID to be leveraged by the UK and European Commission. Ms. Kinard coordinated discussion between MHRA and CDRH's Division of Post-market Surveillance to share lessons learned about business intelligence and data mining.

Ms. Kinard held meetings to educate other FDA centers and other Federal and International agencies about UDI:

- Met with X12 experts (CMS, ONC, NCVHS) to discuss the implications of including UDI in claims.
- Met with CMS to understand their internal processes and understand what would be involved with getting UDI into claims payment systems.
- Met with ONC representative to understand the various UDI stakeholders that will drive UDI adoption. Advocated on behalf of these groups and individuals to be workgroup members and panelists for the Brookings Institute sub-project.
- Established relationship with CAQH (Council on Affordable Quality Healthcare) to set the groundwork for potentially including UDI in bundled payments.
- Held sessions with adverse event system business owners and MedSun (hospital partnership program for adverse event reporting) to inform them of timelines and benefits of including UDI in their systems.
- Advised the CDRH Master Data Management efforts about data integrity and business process concerns.
- Key Contributor of technical expertise about UDI and EHRs in abstract with Duke, Mercy, Mayo and Medtronic: Unique Device Identifiers (UDIs) for Coronary Stent Post-market Surveillance and Comparative Effectiveness Research: Reporting of the Proceedings of the Expert Panel for the FDA's MDEpiNet Demonstration Project.

Mackson Consulting, LLC **2011 – 2012**
Senior Principal

Client: FDA/CDER
Ms. Kinard was the adverse events reporting subject matter expert (as a subcontractor) and led the performance metrics development efforts for FAERS (FDA's Adverse Events Reporting System) with CDER and the Office of Information Management (OIM). She was brought in to turn-around an ailing project several months prior to go-live, and brought the testing and development teams together through creation and standardization of use cases and performance metrics for CDER's Oracle AERS implementation.

Booz Allen Hamilton **2010 – 2011**
Associate

Client: FDA/CDRH
Ms. Kinard excelled with the FDA UDI Team as the Project Manager for the congressionally justified Unique Device Identification Database (UDID). This effort included education of and collaboration with stakeholders presiding over numerous clinical information systems. Stakeholders included Dun & Bradstreet, GS1, SNOMED, Kaiser Permanente, Medtronic, Mercy, and Sentinel.

She advised FDA senior management on cross-division and cross agency communication with regard to the CDRH FAERS requirements and Oracle AERS requirements' impact on workflows and systems. Recommendations included stakeholder management for projects that reach across multiple agencies and divisions with differing goals and motivations, and evaluating the full lifecycle of a medical device from pre-market approval and device listing, through delivery, device use and logging within the EHR (electronic health record), and reporting on adverse events that may lead to recall.

Ms. Kinard managed strategic milestones with the project officer across Drugs, Devices, Biologics, and Office of Combination Products to ensure that CDRH's goals for MAUDE were communicated with the FDA's Adverse Events Reporting System's (FAERS for CDER and CBER) project team members, OMB, and sub-contractors.

Client: Centers for Medicare & Medicaid Services (CMS)
Ms. Kinard advised the CMS Program Integrity Group around Part C (Managed Care) and D (Prescription Drug) program vulnerabilities.

- Briefings focused on the Fraud Waste and Abuse Detection (FWAD) methodology used by the Medicare Integrity Contractors (MEDICs) to determine justifiable metrics for audit targets.
- Subject matter expertise provided in the area of Durable Medical Equipment Prosthetics and Orthotics Suppliers (DMEPOS)—the highest source area of fraudulent claims (~$30-40 billion per year).
- CMS subject matter expert to other Booz Allen teams based at the National Institutes of Health (NIH), the Navy, and the Social Security Administration (SSA).

CGI Federal, Senior Consultant **2008 – 2010**

Client: CMS (both Medicare and Medicaid)
Managed combined teams (prime contractor) in separate locations comprised of technical and functional analysts for a $29 million fraud identification project at HHS via the Centers for Medicare & Medicaid Services (CMS). This project is one of the cornerstones of current government healthcare funding initiatives to streamline processes and improve efficiencies through the use of healthcare informatics and standardization of institutional capabilities.

- Team Lead for the PECOS Durable Medical Equipment (DMEPOS) project, aimed at reducing fraud by more than $10 billion per year through the use of data matching integrity tools.
- Project Lead for the Unified Provider Enrollment Process project (combining Medicaid provider enrollment with PECOS--the Medicare provider enrollment system).

Kaiser Permanente IT **2005 – 2008**
Business Segment Partner

Program Management and Business Communication

- Mid-Atlantic liaison for process improvement to streamline the efficiencies through standardization and communication of best practices. Created IT best practices that were adopted enterprise-wide.
- Provided leadership and oversight of full software development lifecycle projects including an Optical point of sale system, Medicare Risk Assessment Tracking System, Employee Health and Infection Control (HIPAA), Provider Credentialing and Population Care Management. Regulatory project releases included HEDIS, NCQA, Clinical Quality Scorecard, and numerous Disease Registries (data exchange and matching).

Enterprise Strategy and Communications Planning

- Led effort for Kaiser's Mid-Atlantic Region to develop a tool for multi-year strategy planning, resource management, LOE estimation and budget allocation for over 100 regional and national IT initiatives.
- Identified gaps in multi-million dollar processes that enabled $300K+ revenue return and cost savings.
- Advised the corporate office on the resource and budget planning custom software application.

Business Process Improvement

- Identified and led review of six major business processes requiring substantial re-engineering; presented technical solutions to regional senior leadership, board of directors, and the Enterprise Operations group.
- Worked as a Subject Matter Expert facilitating creation of web portals, determining security protocols, trouble-shooting issues for the Availability Program Office, and developing performance metrics.

National Association of Social Workers **2002 – 2004**
Insurance Trust Manager

- Managed professional liability cases for social worker members to determine if they should be able to maintain their policies after legal action.

Medialink Worldwide, Inc. **2000 – 2001**
Account Manager

Crisis Communications and Account Management

- Managed broadcast news stories for Firestone (tire recall), Wyeth (drug recall), Eli Lilly (drug recall), IBM Websphere (product launch), Cisco (partnership with Visa), Energy Star (public service announcement campaign), AOL, NASCAR, and the U.S. Department of Education.
- Initiated business with Booz Allen Hamilton to produce the U.S. Army Industry Day Webcast, which was viewed by 18,000 people, received recognition from the Secretary of the Army and Booz Allen Hamilton, and earned $50,000 for Medialink for the one-day event. This event launched eArmyUniversity (http://www.earmyu.com), the online education initiative provided by universities nationwide to U.S. Army personnel globally.

Kaplan Educational Centers **1997 - 2000**
Manager

Glatfelter Insurance Group **1994 – 1997**
Risk Management Intern

- Worked with Underwriting and Risk Management divisions to determine whether the on-site surveys were held frequently enough to manage risk in fire departments. Developed new audit rules for Risk Management Department.

Device Events Media Coverage

https://www.nytimes.com/2023/04/16/style/coolsculpting-side-effect-risks.html

https://www.startribune.com/how-medtronics-billion-dollar-heartware-device-went-bust/600188914/

https://www.medtechdive.com/news/experts-question-fdas-final-recall-guidance/621530/

https://www.youtube.com/watch?v=nnhjAbdLodY

https://www.medicaldesignandoutsourcing.com/fda-says-philips-knew-about-toxic-foam-for-years-before-massive-recall/

https://www.marketwatch.com/story/beleaguered-fda-in-talks-for-drug-company-funding-11626177049?mod=home-page

https://www.thebrockovichreport.com/p/what-the-fda-doesnt-tell-you

https://harpers.org/archive/2021/03/in-the-net-hernia-mesh/?fbclid=IwAR14m5Qq_r-FpOia4tioUqE1W0BKzxwnhl2OAG5Zgjigb0WSJHTBGD8H2Zs

https://www.baltimoresun.com/business/bs-bz-coronavirus-ambu-scope-maker-maryland-20210430-2ifihtbjvnd3dgqi6jlinjcbzy-story.html

https://www.medicaldesignandoutsourcing.com/hhs-shoots-down-flawed-plan-to-let-some-devices-skip-review/

https://www.medicaldesignandoutsourcing.com/hhs-could-make-permanent-pandemic-related-exemptions-for-some-devices/

https://www.consumerreports.org/diabetes/when-diabetes-devices-fail/

https://www.massdevice.com/fda-updates-adverse-event-database/

https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2752362

https://fortune.com/longform/breast-implants-dangerous-allergan-abbvie-acquisition/?j16sc8

https://www.massdevice.com/study-abbott-edwards-may-have-mislabeled-hundreds-of-patient-deaths/

https://www.icij.org/investigations/implant-files/breast-implant-injuries-kept-hidden-as-new-health-threats-surface/

https://www.nytimes.com/2018/07/20/health/bayer-essure-birth-control.html

http://bleedingedgedoc.com/the-bleeding-edge-hero-of-the-week-madris-tomes/

https://www.icij.org/investigations/implant-files/resources-for-patients-and-frequently-asked-questions/

The Danger Within Us, Lenzer, Jeanne. Tomes, Madris (contributor)

https://khn.org/news/hidden-fda-database-medical-device-injuries-malfunctions/

http://www.startribune.com/fda-releases-millions-of-records-of-incidents-involving-medical-devices/511631502/

https://khn.org/news/fda-chief-calls-for-release-of-all-data-tracking-problems-with-medical-devices/

https://www.nytimes.com/2017/07/11/health/fda-medical-device-problems-rules.html?_r=0

https://www.medicaldesignandoutsourcing.com/how-is-the-partial-government-shutdown-affecting-fda/

https://www.washingtonpost.com/sf/style/2017/07/26/essure/?noredirect=on

https://www.fda.gov/media/122878/download

https://www.azfamily.com/news/investigations/breast_implant_illness_investigation/decoded-fda-data-dump-reveals-medical-devices-with-most-reported/article_49e1eee4-cebf-11e9-9859-ffca4492b9b6.html

https://www.medicaldesignandoutsourcing.com/medtech-predictions-2019/2/

https://www.cnn.com/2018/04/09/health/fda-restricts-essure-device/index.html

https://www.mddionline.com/fda-spoke-and-power-morcellator-use-dropped

https://www.massdevice.com/report-fda-panel-wants-more-extensive-data-quality-of-life-outcomes-for-vaginal-mesh-products/

http://www.startribune.com/fda-proposes-allowing-medical-device-makers-to-summarize-malfunctions/475021143/

http://www.startribune.com/fda-protocols-allow-medical-device-makers-to-keep-adverse-events-out-of-view/397256291/

https://www.meshmedicaldevicenewsdesk.com/fdas-maude-work/

https://www.reuters.com/article/us-bayer-essure-fda/fda-likely-underestimated-fetal-deaths-from-essure-analyst-idUSKCN0VR019

https://www.deviceevents.com/device-events-featured-cnbc-power-lunch/

https://finance.yahoo.com/news/health-companies-label-thousands-patient-175834758.html

https://www.raps.org/regulatory-focus%E2%84%A2/news-articles/2016/2/congressman,-consultant-discuss-goals-in-raising-claims-about-essure

http://deviceevents.com/opening-yourself-up-for-trouble-the-untested-world-of-medical-devices/

"You Don't Know What You Don't Know" Tomes, Madris. Health Watch USA Annual Conference, 2017.

https://www.lawyersandsettlements.com/articles/essure-side-effects/essure-problems-women-bring-fdas-data-meeting-that-fda-were-unaw-22876.html

https://www.yorkdispatch.com/story/news/health/2016/06/15/fda-discusses-devices-linked-infections-york/85821866/

https://www.buzzfeed.com/azeenghorayshi/fda-essure-sterilization-critics?utm_term=.peja0oNOX#.dwYbXx4m1

http://www.center4research.org/morcellator-cancer-reports-drop-essure-reports-rise/

https://www.huffingtonpost.com/entry/opinion-block-essure-contraception-fda_us_5abe8ec0e4b0f112dc9c2e69

https://www.ydr.com/story/news/2017/10/11/who-madris-tomes-whose-company-won-100-000-investment-aol-co-founder-steve-case/753273001/

DEVICE EVENTS

Dental Implant Post-Market Surveillance Report

BACKGROUND:

Adverse event reports date back to 1995 when the FDA created MAUDE, its adverse event reporting database. MAUDE data is publicly available, but the search options only allow for searches of the last 10 years. Since dental implants have been used and reported long before 2012, searching all years becomes critical. MAUDE searches are limited and do not allow for searches of multiple side effects. MAUDE also only returns 500 reports for any given search, making it difficult to analyze reporting patterns in any meaningful way. Device Events was created to provide all MAUDE data in an easy-to-use search engine that allows searches of all 15.5 million reports submitted to the FDA since 1995.

The FDA redacts the reports for protected health information (indicated as b6) and trade secrets (indicated as b4) prior to making them public so all Device Events' data is stripped of event location, hospital name, physician name and patient name.

When adverse event reports are submitted to the FDA, the submitter does not always know the model number, catalog number, or lot number for a device and typically reports as much as possible to identify the suspect device. For that reason, searches have to be expanded to allow for these unknowns. Device Events has the ability to search all fields of a report, unlike the FDA's MAUDE which only allows a search on pre-defined fields. Sometimes when the brand name of a device is not known, the narrative will still provide enough information to identify the device.

SCOPE:

There are two ways in which adverse events could be reported for dental implants:

- Medical Device Reports (MDRs)—searchable in the MAUDE database and updated each month
- Alternative Summary Reports (ASRs)—quarterly spreadsheets submitted to the FDA from 1997 to 2019 which became publicly available on June 26, 2019

SEARCH METHODOLOGY:

Most dental implants are classified under the product code of DZE, regardless of the materials in the device.

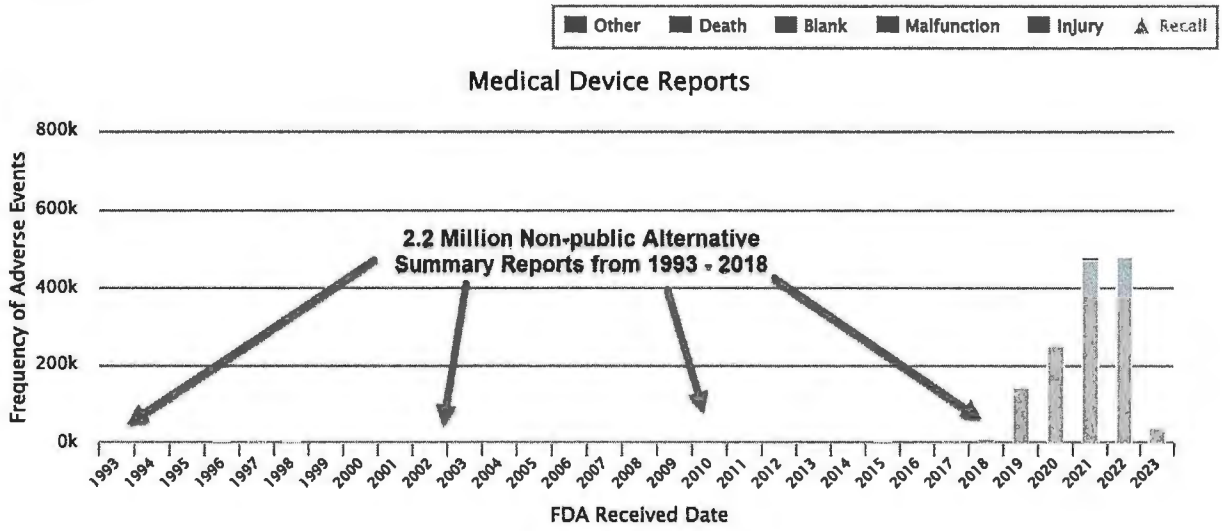
Product Code	Product Code Name
DZE	Implant, Endosseous, Root-Form

There is a second product code for abutments—NHA. The issues with abutments vary from dental implants enough that it should be a separate report/analysis.

Product Code	Product Code Name
NHA	Abutment, Implant, Dental, Endosseous

DENTAL IMPLANT ADVERSE EVENT REPORTS:

This timeline covers all brands of dental implants reported to the FDA individually via MDR. Alternative Summary Reporting of adverse events will be covered later in this report. Up until June 2019, anyone searching for MDRs in the FDA's MAUDE database would have surmised that dental implants had very few issues.



The MDRs were classified by the reporter as injury, malfunction or death. Through January 31, 2023, there were 1.5 million reports to the FDA. The 2.2 million alternative summary reports were not made available until June 2019.

DEVICE EVENTS

Report Type

Check All | Uncheck All

- [x] Injury (1,425,405)
- [x] Malfunction (21,914)
- [x] Other (568)
- [x] *blank* (98)
- [x] Death (53)

The MDRs contain the report source as follows:

Report Source

Check All | Uncheck All

- [x] Manufacturer Report (1,139,703)
- [x] Distributor Report (308,177)
- [x] Voluntary Report (149)
- [x] User Facility Report (9)

They also contain the reporter's occupation. Although there are over 1.3 million reports from dentists, those dentists reported the adverse event to the manufacturer rather than reporting directly to the FDA.

DEVICE EVENTS

Reporter Occupation

Check All | Uncheck All

- ☑ Dentist (1,386,300)
- ☑ Other (36,135)
- ☑ *blank* (16,366)
- ☑ Other Health Care Prof... (6,083)
- ☑ Physician (1,582)
- ☑ Dental Assistant (772)
- ☑ Not Applicable (252)
- ☑ Physician Assistant (168)
- ☑ Unknown (128)
- ☑ Patient (77)
- ☑ Nurse (49)
- ☑ Health Professional (46)
- ☑ Biomedical Engineer (41)
- ☑ Risk Manager (7)
- ☑ Medical Equipment Comp... (6)
- ☑ Dental Hygienist (5)
- ☑ Phlebotomist (4)
- ☑ Attorney (3)
- ☑ No Information (3)
- ☑ Patient Family Member ... (3)

ALTERNATIVE SUMMARY REPORTING (PRE-2019):

The FDA previously permitted some manufacturers to apply for exemptions to the standard MDRs that are found in MAUDE. The FDA allowed certain companies to instead report a device by ASR. This program was ended in early 2019 and the reports that had never been available for over 20 years were made public.

The format of the ASRs was a single spreadsheet by year that contained all device types and was coded. Some spreadsheets contained hundreds of thousands of rows. This is a screenshot of the 2016 spreadsheet shown as an example. There were over 2 million rows (adverse events) in 2016 alone for all device types. They are not separated by device type or company.

DEVICE EVENTS

1997026	9612468	ASTRA TECI	1425478	11/26/2015	IN	2408	2015	4 I	24940	DZE	OsseoSpeed¿ TX 4.0 S -	24940
1997026	9612468	ASTRA TECI	1426339	1/2/2016	IN	1158;2993	2015	4 I	25263	DZE	OsseoSpeed EV 4.2 C -	25263
1997030	1222315	STRAUMAN	1.00E+11	4/30/2015	IN	1260	2015	1 S	033.452S	DZE	"SP Impl. ¿3.3 RN, SLA(	033.452S
1997030	1222315	STRAUMAN	1.00E+11	4/11/2014	IN	1260	2015	1 S	043.762S	DZE	"TE, ¿ 4.1 mm, RN, SLA	043.762S
1997030	1222315	STRAUMAN	1.00E+11	3/24/2015	IN	1260	2015	1 S	043.152S	DZE	"SP, ¿ 3.3 mm, RN, SLA	043.152S
1997030	1222315	STRAUMAN	1.00E+11	10/1/2014	IN	2993	2015	1 I	21.6408	DZE	"BL, ¿ 4.8 mm, RC, SLA	21.6408
1997030	1222315	STRAUMAN	1.00E+11	10/18/2014	IN	1316	2015	1 I	043.066S	DZE	"SP ¿ 4.8mm RN, SLA¿	043.066S
1997030	1222315	STRAUMAN	1.00E+11	11/1/2014	IN	2993	2015	1 I	21.6308	DZE	"BL, ¿ 4.8mm RC, SLAct	21.6308
1997030	1222315	STRAUMAN	1.00E+11	11/17/2014	IN	1863	2015	1 I	21.441	DZE	"BL, ¿ 4.1 mm, RC, SLA	21.441
1997030	1222315	STRAUMAN	1.00E+11	11/23/2014	IN	1863	2015	1 I	033.512S	DZE	"SP ¿ 3.3mm RN, SLAct	033.512S
1997030	1222315	STRAUMAN	1.00E+11	11/24/2014	IN	1863	2015	1 I	21.4412	DZE	"BL, ¿ 4.1 mm, RC, SLA	21.4412
1997030	1222315	STRAUMAN	1.00E+11	11/24/2014	IN	1863	2015	1 I	033.451S	DZE	"SP Impl. ¿3.3 RN, SLA(	033.451S
1997030	1222315	STRAUMAN	1.00E+11	11/24/2014	IN	1863	2015	1 I	043.162S	DZE	"SP ¿ 4.1mm RN, SLA¿	043.162S

Exemptions were typically granted by the FDA to submit an ASR for well-known, minor device issues that occur frequently. The program ended because the FDA felt it was being used incorrectly by several manufacturers.

Although the ASR program ended, a newer program called Voluntary Malfunction Summary Reporting (VMSR) had already gained congressional approval and was instituted in its place. The FDA did not grant an exemption to dental implant manufacturers to use this new program, possibly because the vast majority of the ASRs that had been submitted were serious injuries, not malfunctions. It is likely the FDA wants to receive MDRs which are more detailed (and include a narrative) so that they may better evaluate the risks of dental implants in the future. MDRs are reported within 5-30 days and summary reports are quarterly. MDRs allow the FDA to see the reports more quickly.

DENTAL IMPLANT AND ABUTMENT ISSUES:

Within the Device Events software platform, all MDRs and ASRs have been added to a single searchable interface. When combined, there are 3.6 million adverse event reports and 176 recalls. **Dental implants are the single most reported device to the FDA since 1995.**

Record Type

Check All | Uncheck All

- ☑ Alt. Summary Reports (2,185,222)
- ☑ Medical Device Reports (1,448,038)
- ☑ Recalls (176)

When an adverse event is submitted to the FDA by the manufacturer it contains 2 different types of codes:

- Device Problem Codes
- Patient Problem Codes (outcomes)

Patient Problem Codes have only been publicly available for ASRs since January 2022 and for MDRs since September 2020. Prior to that they were redacted by the FDA. The workaround for this was that MDRs

contain a narrative explaining the event and that narrative could be searched for keywords. ASRs, however, do not contain narrative text.

Not all reports are coded. Sometimes the only way to understand the outcome is to read the narrative.

The following screenshot captures the Device Problem Codes for reports that were coded.

Device Problem

Check All | Uncheck All

- ☑ Failure To Osseointegrate (2,334,087)
- ☑ Loss Of Osseointegration (826,486)
- ☑ Osseointegration Problem (154,958)
- ☑ Implant, Removal Of (130,261)
- ☑ Adverse Event Without ... (103,877)
- ☑ Fracture (70,808)
- ☑ Positioning Failure (22,303)
- ☑ Implant Mobility Nos (... (14,115)
- ☑ Use Of Device Problem (13,229)
- ☑ Difficult To Insert (9,838)
- ☑ *blank* (6,979)
- ☑ Improper Or Incorrect ... (6,822)
- ☑ Mechanical Problem (6,700)
- ☑ Positioning Problem (5,373)
- ☑ Insufficient Information (4,767)
- ☑ Separation Failure (2,767)
- ☑ Unknown (for Use When ... (2,003)
- ☑ Difficult To Remove (1,987)
- ☑ Positioning Failure (1,923)
- ☑ Material Deformation (1,719)
- ☑ Malposition Of Device (1,554)
- ☑ Separation Failure (1,506)
- ☑ Malfunction (1,459)
- ☑ Product Quality Problem (1,424)
- ☑ Crack (1,408)
- ☑ Break (1,211)
- ☑ Unintended Movement (1,069)
- ☑ Explanted (918)
- ☑ Malposition Of Device (734)
- ☑ Other (for Use When An... (726)
- ☑ Loosening Of Implant N... (693)
- ☑ Failure To Adhere Or Bond (578)
- ☑ Component(s), Broken (557)
- ☑ Device Damaged By Anot... (541)

There can be multiple Device Problem Codes as well as multiple Patient Problem Codes in a single report.

The Patient Problem Codes (outcomes) are:

Patient Problem

Check All | Uncheck All

- ☑ Failure Of Implant (1,792,431)
- ☑ Pain (334,579)
- ☑ Tissue Damage (328,267)
- ☑ Unspecified Infection (296,771)
- ☑ No Information (228,459)
- ☑ No Clinical Signs, Sym... (216,422)
- ☑ Fibrosis (133,803)
- ☑ Unknown (for Use When ... (106,638)
- ☑ Contraindicated Patient (80,395)
- ☑ Inflammation (63,144)
- ☑ No Patient Involvement (53,813)
- ☑ Hemorrhage/bleeding (48,573)
- ☑ Inadequate Osseointegr... (33,232)
- ☑ No Consequences Or Imp... (32,255)
- ☑ Fistula (27,787)
- ☑ Discomfort (27,195)
- ☑ Numbness (27,072)
- ☑ Osteopenia/ Osteoporosis (22,850)
- ☑ Swelling/ Edema (22,706)
- ☑ Abscess (19,097)
- ☑ Insufficient Information (17,050)
- ☑ Osteolysis (16,138)
- ☑ Swelling (16,049)
- ☑ No Code Available (15,824)
- ☑ Edema (14,501)
- ☑ Bacterial Infection (14,199)
- ☑ Increased Sensitivity (11,341)
- ☑ No Known Impact Or Con... (10,720)
- ☑ Other (for Use When An... (10,237)
- ☑ Erosion (9,796)
- ☑ Hypersensitivity/aller... (8,582)
- ☑ Sinus Perforation (6,172)
- ☑ Complaint, Ill-defined (5,839)
- ☑ Wound Dehiscence (5,662)
- ☑ Bleeding (5,307)
- ☑ Soreness (4,741)
- ☑ Osteointegration, Inad... (3,794)
- ☑ Pocket Erosion (3,401)
- ☑ Granuloma (2,647)

The companies are ordered below based on the numbers of adverse events (MDRs and ASRs) they have submitted to the FDA:

Company Name

Check All | Uncheck All

- ☑ Nobel Biocare (1,350,450)
- ☑ Straumann (906,415)
- ☑ Zimmer Biomet (617,067)
- ☑ Dentsply (394,768)
- ☑ Altatec (102,844)
- ☑ Biohorizons (88,810)
- ☑ Implant Direct (63,592)
- ☑ Biohorizons Implant Sy... (47,090)
- ☑ Keystone Dental (42,965)
- ☑ Lifecore (25,894)

Manufacturers do not provide sales figures to the FDA, so often there is no denominator for them to use to calculate failure rates. For this report, we obtained sales data from iData. The adverse event failure rates are calculated below as a percentage of sales.

DEVICE EVENTS

Year	Sales	MDRs (Publicly Viewable)	ASRs (released June 2019)	Total ASRs & MDRs	% vs. Sales
2010	1,924,493	360	145,788	146,148	8%
2011	2,029,611	361	154,530	154,891	8%
2012	2,116,117	358	176,153	176,511	8%
2013	2,262,505	391	176,503	176,894	8%
2014	2,400,271	1,124	201,849	202,973	8%
2015	2,546,042	2,893	212,893	215,786	8%
2016	2,731,028	1,110	263,082	264,192	10%
2017	2,969,987	9,717	278,622	288,339	10%
2018	3,224,566	12,823	122,766	135,589	4%
2019	3,508,816	146,659	*10	146,669	4%
2020	2,826,071	255,197	-	255,197	9%
2021	3,432,808	477,850	-	477,850	14%
2022	3,727,921	483,228	-	483,228	13%
81% of MDRs and ASRs are injury reports					
Sales data provided by iData					
MDR and ASR data provided by Device Events					

Note: The FDA created a webpage about dental implants in 2021 only after being alerted by a television news journalist that there was no patient information on the FDA site, and that a CBS news story was forthcoming. The FDA, to date, has still has not convened a scientific panel to discuss the risk profile of dental implants.

Data Set Prepared for:

SIOUXLAND oral & maxillofacial surgery

Table of Contents†

Description:

This data set presents a quantitative analysis of the U.S. Dental Implant Market in terms of units sold, from 2010-2022.

Regions Analysed*:

- U.S.

Reporting Period:

- 2010 - 2022

Market Data

Dental Implant Market by Segment

- Dental Implant Units Sold
- Final Abutment Units Sold
- Dental Implant End-User Analysis

Metrics

- Units Sold
- Growth
- End-User Analysis

iData

U.S. Historical Unit Sales - Dental Implant & Final Abutment Market

U.S. Unit Sales - Dental Implant & Final Abutment Market

Year	Dental Implants Units Sold	Growth (%)	Final Abutments Units Sold	Growth (%)
2010	1,924,493		1,742,883	
2011	2,029,611	5.5%	1,839,920	5.6%
2012	2,116,117	4.3%	1,920,262	4.4%
2013	2,262,505	6.9%	2,055,156	7.0%
2014	2,400,271	6.1%	2,182,479	6.2%
2015	2,546,042	6.1%	2,317,340	6.2%
2016	2,731,028	7.3%	2,508,298	8.2%
2017	2,969,987	8.7%	2,728,728	8.8%
2018	3,224,566	8.6%	2,946,902	8.0%
2019	3,508,816	8.8%	3,210,732	9.0%
2020	2,826,071	-19.5%	2,608,796	-18.7%
2021	3,432,808	21.5%	3,193,958	22.4%
2022	3,727,921	8.6%	3,493,179	9.4%

Source: IData Research

Implants Placed by Specialization

Year	Dental Implants Units Sold	Growth (%)	Number of GPs Placing Implants	Percentage of Implants Placed by GPs (%)	Number of Specialists Placing Implants	Percentage of Implants Placed by Specialists (%)	Number of Implants placed per GP per Year	Number of Implants placed per Specialist per Year
2010	1,924,493		24,943	28.3%	20,600	71.7%	21.8	67.0
2011	2,029,611	5.5%	27,659	30.1%	21,115	69.9%	22.1	67.2
2012	2,116,117	4.3%	30,551	32.2%	21,685	67.8%	22.3	66.2
2013	2,262,505	6.9%	30,536	30.4%	23,370	69.6%	22.5	67.4
2014	2,400,271	6.1%	32,521	30.8%	24,465	69.2%	22.7	67.9
2015	2,546,042	6.1%	32,896	28.9%	24,581	71.1%	22.4	73.6
2016	2,731,028	7.3%	33,963	28.2%	25,838	71.8%	22.7	75.9
2017	2,969,987	8.7%	35,289	27.4%	22,393	72.6%	23.0	96.3
2018	3,224,566	8.6%	37,685	27.3%	22,622	72.7%	23.4	103.6
2019	3,508,816	8.8%	40,249	27.2%	24,210	72.8%	23.7	105.5
2020	2,826,071	-19.5%	43,026	28.8%	23,121	71.2%	18.9	87.1
2021	3,432,808	21.5%	45,360	31.8%	23,156	68.2%	24.1	101.0
2022	3,727,921	8.6%	47,704	31.3%	23,191	68.7%	24.5	110.4

Source: IData Research

Number of Implants placed by Occupation

Year	Number of Implants Placed by GPs	Number of Implants Placed by Specialists	Total Number of Implants Placed
2010	544,553	1,379,941	1,924,493
2011	609,947	1,419,664	2,029,611
2012	680,523	1,435,594	2,116,117
2013	687,051	1,575,454	2,262,505
2014	739,039	1,661,232	2,400,271
2015	735,743	1,810,299	2,546,042
2016	771,017	1,960,011	2,731,028
2017	813,130	2,156,858	2,969,987
2018	881,352	2,343,214	3,224,566
2019	955,442	2,553,375	3,508,816
2020	812,614	2,013,457	2,826,071
2021	1,092,932	2,339,876	3,432,808
2022	1,166,653	2,561,268	3,727,921

Source: IData Research

GPs Placing Implants

Year	Number of GPs in the U.S.	Growth (%)	Percentage Placing Implants (%)	Percentage Placing >30 Implants Per Year (%)	Percentage Restoring Implants (%)
2010	153,214		16.3%	4.8%	53.9%
2011	155,157	1.3%	17.8%	5.6%	55.8%
2012	157,228	1.3%	19.4%	6.7%	57.6%
2013	159,722	1.6%	19.1%	5.8%	52.3%
2014	161,853	1.3%	20.1%	6.7%	53.8%
2015	156,298	-3.4%	21.0%	8.9%	56.6%
2016	153,781	-1.6%	22.1%	8.9%	58.1%
2017	151,014	-1.8%	23.4%	11.8%	60.2%
2018	153,476	1.6%	24.6%	11.8%	62.0%
2019	155,926	1.6%	25.8%	13.6%	63.8%
2020	158,480	1.6%	27.1%	15.7%	65.7%
2021	159,263	0.5%	28.5%	16.3%	67.3%
2022	160,050	0.5%	29.8%	17.0%	69.0%

Source: IData Research

Specialists Placing Implants

Year	Number of Specialists in the U.S.	Growth (%)	Percentage Placing Implants (%)
2010	28,640		71.9%
2011	29,633	3.5%	71.3%
2012	31,313	5.7%	69.3%
2013	34,347	9.7%	68.0%
2014	37,588	9.4%	65.1%
2015	39,570	5.3%	62.1%
2016	40,465	2.3%	63.9%
2017	41,953	3.7%	53.4%
2018	43,397	3.4%	52.1%
2019	44,493	2.5%	54.4%
2020	42,637	-4.2%	54.2%
2021	42,847	0.5%	54.0%
2022	43,059	0.5%	53.9%

Source: IData Research

Research Methodology

iData's 9-Step Methodology

Research published by iData meets the highest standards of quality because each one is a product of our rigorous and systematic 9-Step Research Methodology. This methodology has been shown to consistently

- Solid foundation of data collected from the "bottom up"
- Original primary research that consists of the most up-to-date market data
- Research anchored in quantitative, not just qualitative, research
- Market sizing and forecasts based on procedure volumes
- Focused on the needs and strategic challenges of the industry participants

Step 1: Project Initiation & Team Selection

this preliminary investigation, all staff members involved in the industry meet and discuss the topic in detail. The interdisciplinary research team analyzes the market to identify and anticipate key opportunities and challenges facing the industry. The results of this process are combined with feedback from iData's sales force, consultants measurements, segmentation, and instrumentation, are selected. A preliminary list of key issues and trends is created, and competitors are identified. This step culminates in the selection of the research team members. The success of any research project depends ultimately on the skills of the team members and on their ability to

Lead Analyst

The primary function of the lead analyst is to design and implement the research project. This includes performing or supervising the collection and analysis of the project data. The lead analyst is also responsible for

Support Analyst

The support analyst conducts and assists with data collection and analysis, in cooperation with the lead analyst.

Research Managers

Research managers direct the research projects within their respective industry segments. They function to ensure consistency among research reports, and to manage and support the analysis team. Research managers

Market Consultants

In cases where iData's customers have specific marketing or business needs, market consultants work in conjunction with the customers to develop tailored solutions. Market consultants can also work with customers

Account Managers

Account managers are responsible for ensuring that customer input and feedback is reflected in the results of research projects, including responses to prior research reports and customer requests for future research

Industry Advisors and Key Customers

Where required for specific projects, iData will employ industry advisors and consultants to better handle
It regularly occurs that iData's customers will participate in the research process. They are most often involved in

Step 2: Prepare Data Systems and Perform Secondary Research

Preparing for the data collection process is the start of the research phase: Filing systems, data-input systems and relational databases are developed as needed. The fields are assembled into figures and charts and the

- Internal databases and libraries
- Company annual reports
- U.S. Securities and Exchanges Commission (SEC) filings

- Drug and patent regulatory databases
- U.S. Food and Drug Administration (FDA) Filings
- Government census and national statistical databases
- Procedure databases from hospital and government organizations
- International Trade Databases
- National, regional and hospital-level tender databases
- Government purchase data
- Manufacturer and distributor price lists
- Online sources such as web-casts, press releases and newsletters
- University library affiliations
- Trade associations
- Investor presentations and broker reports
- Product brochures
- Other sources

Next, in consideration of this research and our previous research and industry feedback, the analyst team develops an in-depth Table of Contents to serve as the organizational framework of the market research

Procedure Data Analysis

market size, see trends and forecast the future market. iData uses multiples sources to gather and measure procedures that directly use the products in each market segment. These analyses are done using CPT, HCPCS, DRG, ICD and other regional coding systems that standardize the recording of procedures in many of the

Reimbursement Data

Current and historical trends in insurance policy coverage and government reimbursement rates are reviewed and analyzed to provide additional insight into market trends. iData's internal database of insurance policies and

Pricing Data Analysis

To complement ASP estimates obtained through primary research, iData systematically reviews five key country-specific data sources: hospital purchasing order data, manufacturer and distributor price lists, public tender data,

Step 3: Preparation for Interviews & Questionnaire Design

The core of all iData research reports is primary market research. Interviews with industry insiders represent the single most reliable way to obtain accurate, current data about market conditions, trends, threats and

Before conducting interviews with end-users or industry insiders, studies are carefully designed and tested to

- Readily understandable and avoid unnecessary jargon
- Yield all of the required information
- Gather quantitative data in the same units
- Encourage the cooperation of respondents
- Elicit specific and relevant information
- Explore the respondent's subject expertise
- Guard against industry biases and unintentional over or under estimations

Step 4: Performing Primary Research

At this stage, interviews are performed using contacts and information acquired in the secondary research phase. Valuable strategic information is obtained from market participants, and is then used to modify market

Sources Consulted

During primary research, our analysts consult with a variety of industry and end-user sources in order to foster

- Product Managers
- Marketing Managers and Directors
- C-level Executives
- Vice Presidents
- Physicians and Specialists
- Key Opinion Leaders (KOLs)
- End Users
- Hospitals and Group Purchasing Organizations

Bottom-up Approach

that it contains. This approach allows us to provide our clients with the most accurate results, while also deepening the segmentation and coverage of data in our market research.

The annual shipments or revenues of market competitors are also obtained by interviews, and competitor market sizes and associated forecasts are added to obtain the total market estimate. Furthermore, the bottom-

Cross-Verification to Identify Anomalies

analysts are trained to detect when misleading or incorrect information is being introduced into an interview. Furthermore, wherever possible iData cross-verifies all data from each respondent by conducting multiple other interviews in the same market. The questionable information is confirmed by speaking to other competitors, end·

Measuring Growth Rate

creating a 10-year total market characterization period. Growth rates are estimated using the compound annual growth rate (CAGR) calculation, which accounts for both the annual changes in market value, and changes in the growth rate. The CAGR is the average yearly growth rate that would be required to yield the forecasted value,

Market Segments

Interviews with industry participants allow our analysts to ensure that market segmentation and products are organized in a logical way. Ensuring proper segmentation also reduces the possibility of biases or inaccuracies

Step 5: Research Analysis: Establishing Baseline Estimates

Following the completion of the primary research phase, the collected information must be synthesized into an accurate view of the market status. The most important question is the current state of the market; this must be

- Procedure volume
- Market size
- Market share
- Historical market growth rate
- Units sold
- Average selling prices
- Intensity of competition
- Strategic activities such as M&A deals and licensing agreements
- Market demand due to unmet needs
- Market Maturity
- Competitive activities

Step 6: Market Forecast and Analysis

opinions of industry experts to forecast future market values. Data alone is often an inadequate forecasting method, since the underlying information sometimes cannot be found. Moreover, market history does not necessarily reflect market future — new trends, technologies and treatments may arise that can render historically based inferences meaningless.

In contrast, expert opinions have been found to incorporate the changes in market drivers and limiters in a more reliable way. The experts consulted include, among others, key customers, government regulators, marketing managers, sales managers, Research and Development managers, business development managers, market

Additional Insights and Analysis

The research we provide not only features our specific market forecasts, but also includes significant analysis and commentary on many different market factors. Our analysts use insights from these categories to develop

- Market Drivers & Limiters
- Clinical Trials and Product Pipelines
- Technological Trends and Innovations
- Regulatory Trends
- Reimbursement Trends
- Economic Conditions
- Competitive Landscape and Mergers/Acquisitions
- New Entrants into the Market
- Consumer Demographics

variables in the marketplace and it is virtually impossible to guarantee specific predicted values. As such our forecasts are to be considered a "best effort" at market prediction. Fortunately, completely unexpected events are generally rare and often tend to affect the timing of the market trends rather than changing the trends themselves. The key test of forecast credibility is whether or not the analyst team has integrated all the critical elements of the market into the forecast. If the important present and future market drivers and limiters have been properly considered, the forecast will have strong credibility. In practice, it is the direction and approximate

Step 7: Identify Strategic Opportunities

iData analysts identify in broad terms why some companies are gaining or losing share within a given market segment. Changes in market share are the most telling indication of the effectiveness of corporate strategies; it is important to identify those who are succeeding in the market and those who are failing, and the cause of the market flux.

It is from these insights that our data and information helps our clients to identify strategic opportunities and threats within the market. Applying the information provided in our research is how we empower our clients to

- Gauging timing and size of research and development activities
- Helping production departments plan to gear up or gear down to meet demand
- Assessing how quickly to increase or decrease sales force activities
- Aiding in allocating management attention
- Creating strategies for new product development
- Supporting investment decisions
- Aiding in the business planning process
- Serving as a credible, independent check on company internal forecasts
- Supporting acquisition strategies
- Assisting in allocating marketing investments

- Supporting company financial and cash flow planning

Step 8: Final Review and Market Release

An integral part of the iData research methodology is a built-in philosophy of quality control and continuous

Quality Control

Each analyst team bears final responsibility for the quality and accuracy of their reports. This is achieved through a process of cross-verification and comparison among alternative estimators. Estimates are thus verified and

Final Review

detailed review of the final research. Care is taken to ensure that all issues have been covered, all measurements have been included, and the conclusions and analysis are logical and sound. The report must be found to be as accurate, comprehensive and as detailed as possible at the time of publication. Any approved changes or

Step 9: Customer Feedback and Market Monitoring

iData's philosophy of continuous improvement requires that reports be monitored after publication for

Customer Feedback

research reports. Clarification of any issues or questions regarding the report is gladly provided to our customers at no cost. iData research teams immediately correct any reported inconsistencies, mistakes or other errors to ensure that reports are accurate and up-to-date. We consider all of our customers as partners in advancing the

Continuous Market Monitoring

which research has been performed, an enduring market research relationship is fostered. Reports are updated and corrected as new or better information is discovered. This means that our clients will always have a reliable source for up-to-date research, and our analysts are always available to help clients with their unique research

Advanced Implant Dentistry Programs in the United States

The institutions listed indicated in AAID's 2017 survey that they currently offer full-time post-doctoral education in implant dentistry.

Institution	Location	Type of Program	Time Frame	Details	Contact
Brookdale University Hospital Medical Center	Brooklyn, New York	Advanced Education Program	2 years	Integrates the principles of surgery, prosthetics, and implantology to achieve state-of-the-art results in patient care	Vito A. Cardo, DDS vcardo@brookdale.edu
Harvard University	Boston, Massachusetts	Certificate in Implant Dentistry	2 years	Must have dental degree and two years of advanced graduate education in a specialty of dental medicine or three years professional experience.	Dr. German Gallucci german_gallucci@hsdm.harvard.edu
Indiana University	Indianapolis, Indiana	Implant Fellowship	1 year	Includes all aspects of implant dentistry: didactic, laboratory and clinical (surgical and restorative) instruction; research and teaching	dentistry.iu.edu
Loma Linda University	Loma Linda, California	Certificate and Optional MS degree	3 years	Focuses on clinical proficiency in both the surgical placement of dental implants and the complete fabrication of implant-supported restorations	Cynthia Briceno Implantdentistry@llu.edu www.llu.edu/dentistry/implant
North Shore Long Island Jewish Health System	New Hyde Park, New York	Implant Fellowship	1 year	Must complete a GPR program and be licensed or eligible for a license in New York State. Applications are accepted on a rolling basis	Donna Garambone, Dgarambone@nshs.edu www.northshorelij.com
Ohio State University	Columbus, Ohio	Implant Fellowship		Must have completed advanced program in prosthodontics or OMS	dentistry.osu.edu
Southern Illinois University	Alton, Illinois	Implant Fellowship	1 year	25% surgical, 25% implant restorative, 30% other restorative and surgical care, 10% research, 10% teaching	Meagan Gunn megunn@siue.edu www.siue.edu/dentalmedicine/implantprogram/

Advanced Implant Dentistry Programs in the United States

Institution	Location	Type of Program	Time Frame	Details	Contact
Tufts University	Boston, Massachusetts	Implant Fellowship	2 years	1 year on evaluation, treatment planning and restoration, 1 year on surgical placement and site modification	roger.galburt@tufts.edu dental.tufts.edu
University of Pittsburgh	Pittsburgh, Pennsylvania	Implant Fellowship	1 year	The Multidisciplinary Implant Center is a collaboration of several departments within the School of Dental Medicine.	Dr . Mark Ochs, ochsmw@upmc.edu www.dental.pitt.edu
University of North Carolina	Chapel Hill, North Carolina	Advanced Education in Prosthodontics and Implant Fellowship	3 years	Theoretical, research, and clinical experience in surgical implant placement and restoration	Ryan Cook, DDS, MS ryancookddsms@unc.edu
Nova Southeastern University, College of Dental Medicine	Ft. Lauderdale, Florida	Implant Fellowship	1 year	This Implant Dentistry Program is a 1 year program in Implant Dentistry that focuses on implant placement and/or implant restorative dentistry. If the applicant is a Prosthodontist he/she will work in collaboration with the Periodontics Advanced Specialty Program. If the applicant is a Periodontist, he/she will work with the Prosthodontics Specialty Program. If the applicant is only a graduate of DDS,DMD program, they will work with both and must have had a significant amount of exposure to implant restorations.	Dr. William Parker parkwill@nova.edu www.nova.edu

Advanced Implant Dentistry Programs in the United States

Institution	Location	Type of Program	Time Frame	Details	Contact
University of Florida	Gainesville, Florida	Implant Fellowship	1 year	Comprehensive training in the surgical and restorative aspects of Implant Dentistry.	Rodrigo Neiva rneiva@dental.ufl.edu www.dental.ufl.edu
Northwell Health	Manhasset, New York	Implant Dentistry and Advanced Prosthetics	1 year	Clinical fellowship in implant dentistry	William Stewart, DDS, MPH wstewart@northwell.edu www.northwell.edu

Antitrust Referral Analysis
Submittal by Board or Commission

Board or Commission: Ohio State Dental Board

Contact Name: Steve Kochheiser, Deputy Director/Chief Legal Counsel

Date: October 31, 2018

Referral Topic: Dental Specialties Recognition and Advertising Rules

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. The CSI office was codified by ORC 107.52 for agency rule review. Additional scope was added in 2017 under ORC 107.56 which describes actions to be reviewed by the CSI Office for determination of approval or disapproval.

Referral Information

1. **What is the action/proposed action being taken?**

The Ohio State Dental Board ("Board") is changing its specialty recognition and advertisement rules. The new rules will recognize those dentists as specialists who complete an accredited, full-time, post-doctoral education program. Dentists that are recognized as specialists may advertise as a "specialist" or use terms specifically related to their specialty in advertisements (such as endodontist or orthodontist).

2. **In a brief statement explain the factual background, nature, purpose and rationale of the action/proposed action pertaining to this referral.**

The Board currently regulates specialty recognition and advertising by recognizing as specialists those dentists who have completed an accredited post-doctoral education program in one of nine areas of

dentistry recognized by the American Dental Association (ADA). These areas are: orthodontics, oral and maxillofacial surgery, oral and maxillofacial radiology, periodontics, pediatric dentistry, prosthodontics, endodontics, oral pathology, and dental public health. Dentists recognized as specialists may advertise as a "specialist" or by using a term associated with a dental specialty such as "orthodontist" or "endodontist." However, in recent years, additional post-doctoral education programs have developed in specialty areas not recognized by the ADA. For example, the American Board of Dental Specialties currently recognizes specialty certifying boards in the areas of oral implantology/implant dentistry, oral medicine, orofacial pain, and dental anesthesiology. The Ohio State Dental Board seeks to broaden its specialty recognition and advertising rules to include not only dentists who have completed an accredited post-doctoral education program in the nine areas currently recognized by the ADA, but also dentists who have completed an accredited post-doctoral education program in an area of general dentistry not included in the nine specialties recognized by the ADA, as well as dentists who have completed a post-doctoral education or residency program of at least two years in an accredited hospital or dental college.

The purpose of this rule is to continue to protect the public by ensuring that only those dentists who have completed an accredited post-doctoral education program are able to advertise as a specialist. Some dentists receive dental specialty education from continuing education providers that are not accredited by entities approved by the U.S. Department of Education, or other nationally-recognized agencies that accredit hospital training programs. The general public typically does not have knowledge or expertise in the level and types of education completed by dental specialists, and the public can be misled by advertising that represents a dentist as a specialist when the dentist does not have sufficient training in the specialty area. The unaccredited training programs are typically of a shorter duration and do not have the same quality control standards as accredited programs, and the Board cannot be assured of the quality of the training in the absence of accreditation.

The legislature has entrusted the Board with setting the requirements for recognition as a dental specialist. In the Board's expertise, an accredited post-doctoral education ensures a sufficient level of education to consider a dentist a specialist.

3. **Please check all of the following that apply as reasons the action/proposed action is subject to review? (ORC 107.56(B)(1))?**

   ☐ Fixes prices or limits price competition;

   ☐ Divides, allocates or assigns customers or potential customers or geographic markets in this state among members of the occupation regulated by the boards;

   ☐ Excludes present or potential competitors from the occupation regulated by the board;

   ☐ Limits output or supply in this state of any good or service provided by the members of the regulated occupation;

   ☐ Prohibits offering a particular quality-level of a product or service;

   ☒ Restricts advertising or makes it more expensive or less effective;

☐ Substantially reduces the number of firms or providers that can serve a particular set of customers; or

☐ Any other activity that could be subject to state or federal antitrust law if undertaken by private persons.

4. **Is the action/proposed action explicitly compelled or specifically authorized by statute? If so, please list the statute(s).**

The Board is compelled to regulate the practice of dentistry and is authorized to promulgate rules governing the recognition and advertising of dental specialties. Under R.C. section 4715.01, the practice of dentistry includes any person who "advertises to perform" dental operations of any kind. Since the Board regulates the practice of dentistry including the advertising of dental services, the Board may promulgate rules to regulate advertising. Under R.C. section 4715.30(A)(3), the Board may take disciplinary action against an applicant or license holder for, "Advertising services in a false or misleading manner or violating the board's rules governing time, place, and manner of advertising." The Board is also compelled and authorized to establish standards for recognition of specialists pursuant to R.C. section 4715.02, which provides that two Board members "shall be persons recognized as specialists **pursuant to rules adopted by the board.**" R.C. section 4715.02 (emphasis added). Additionally, under R.C. section 4715.03(A), the Board is permitted to make "reasonable rules as it determines necessary pursuant to" R.C. Chapter 119. Thus, the Board is compelled and authorized to promulgate rules regulating the requirements for recognition and advertising of dental specialties.

5. **Is the action/proposed action within the scope of the board or commission's statutorily-delegated general authority to regulate in a given occupation or industry? If so, please describe how it is within scope and reference the statute.**

The proposed rule to regulate the recognition and advertising of dental specialties is within the scope of the Board's statutorily-delegated general authority to regulate the practice of dentistry. Under R.C. 4715.01, the practice of dentistry includes any person who "advertises to perform" dental operations of any kind. Since the Board regulates the practice of dentistry including the advertising of dental services, the Board may promulgate rules to regulate advertising. Under R.C. 4715.30(A)(3), the Board may take disciplinary action against an applicant or license holder for, "Advertising services in a false or misleading manner or violating the board's rules governing time, place, and manner of advertising." As discussed in response to Question 2, the public can be misled by an advertisement representing a dentist as a specialist if the dentist has not had sufficient accredited training in a dental specialty. The Board is also within the scope of the Board's statutorily-delegated general authority to regulate the practice of dentistry to establish standards for recognition of specialists pursuant to R.C. 4715.02, which provides that two Board members "shall be persons recognized as specialists pursuant to rules adopted by the board." Additionally, under R.C. 4715.03(A), the Board is permitted to make "reasonable rules as it determines necessary pursuant to" R.C. Chapter 119. Thus, regulating the recognition and advertising of dental specialties is within the scope of the Board's statutorily-delegated general authority to regulate the practice of dentistry, which includes the recognition of specialists and advertising of dental services.

6. **Please identify the clearly articulated state policy (e.g., health and safety, or consumer protection) in state statute or rule, or any supporting evidence of the harm the action/proposed action is intended to protect against?**

The proposed rule furthers the clearly articulated state policy of setting standards for dental specialists, and protecting dental consumers by regulating the false or misleading advertising of dental specialties. Section 4715.30(A)(3) of the Revised Code provides that the Board may take disciplinary action against a licensee for, "Advertising services in a false or misleading manner or violating the board's rules governing time, place, and manner of advertising[.]" The Board promulgated its advertising rules in O.A.C. Chapter 4715-13, including advertising specialty services. O.A.C. rule 4715-13-01(A) provides, "In order to facilitate the process of informed selection of a dentist by potential consumers of dental services, the holder of a license or certificate issued under this chapter (licensee), or dental organization, in accordance with section 4715.30 of the Revised Code, and the rules and regulations of the Ohio state dental board, may publish advertising statements in print media, or broadcast advertising over FCC-approved radio or television, or via the internet." In O.A.C. rules 4715-13-04 and 4715-13-05, the Board provides rules regarding the advertising of dental specialty services. Thus, the Board, in its expertise, has determined that specific requirements are necessary for a dentist to advertise as a specialist to ensure that consumers of dental specialty services are not misled, and can make a better-informed selection when choosing a dentist.

Evidence was presented to the Board regarding consumer review of dental specialty advertising. The Ohio Dental Association ("ODA") commissioned a survey by Saperstein and Associates to study Ohio residents' views regarding dental specialty education, recognition, and advertising. The results of the ODA survey were presented to the Board during its May 9, 2018 meeting. In the Saperstein survey, participants were asked if they would think that a dentist who advertised as a specialist had completed an accredited residency program following dental school. Depending on which type of dental specialty was referenced in the question, 73 to 90 percent of the participants answered yes. Approximately two-thirds of the participants believed that a dentist who advertised as a specialist was more qualified than a general dentist in their specialty field. The participants in that survey were also asked whether they would be more or less likely to choose a dentist who advertised as a specialist but did not complete an accredited program. Depending on the specialty, 70 to 81 percent of the participants stated that they would be less likely to choose that dentist. Because of evidence that most consumers believe that a dental specialist has completed an accredited training program after dental school, it would be misleading for a dentist to advertise as a specialist without completing an accredited training program.

6a. How does the action/proposed action address the harm or advance the articulated state policy?

The proposed rule focuses on ensuring that dental specialists have a particular level of education rather than allowing a dentist to advertise as a specialist solely on the basis of recognition by a certifying board or trade association. The Board, in its expertise has determined that the level of accredited education is the best method of recognizing a specialist provider of dental services. The proposed rules do not allow

dentists to advertise as a specialist unless they have completed sufficient accredited training to ensure the quality of advanced education in the specialty area. Under the proposed rules, however, a dentist may truthfully advertise that the dentist has been awarded "diplomate" status or other similar credentials by an unaccredited training institution, as long as the dentist includes a disclaimer stating that the organization does not meet the specialty recognition requirements of the Board. This allows the dentist to truthfully advertise non-accredited specialty training, but provides information to allow the consumer to make a more informed decision in selecting a dentist.

8. **If appropriate, explain the action/proposed action's alleged consistency with state or federal antitrust law, which may include a description of how the action or proposed action may affect the number of competitors and those competitors incentive to compete in amount, quality, variety or other aspects of the good or service offered.**

The Board's proposed rule is entirely consistent with state and federal antitrust law. It does not exclude any competitors in the market from practicing dentistry. Anyone possessing a license to practice dentistry in Ohio may perform the same procedures and care, including specialty procedures, as long as they comply with the laws and rules governing the practice of dentistry in Ohio. The proposed rule merely restricts dentists from engaging in certain types of false and misleading advertising; specifically, it prohibits dentists from advertising that they are a specialist when they are, in fact, not.

In reviewing a referred action, pursuant to Section 107.56(D) of the Ohio Revised Code, the Common Sense Initiative Office should determine whether an action referred is supported by, and consistent with, a clearly articulated state policy as expressed in the statutes creating the board or the statutes and rules setting forth the board's powers, authority, and duties. Section 107.56(D)-(E) of the Ohio Revised Code further requires the Common Sense Initiative Office to review the action and approve the action if it is consistent with a clearly articulated state policy or disapprove the action if it is not consistent with a clearly articulated state policy, but rather a pretext for self-dealing.

In the event that private actors in the market engage in collusive activity aimed at restricting advertising to further their own self-interest to the detriment of their competitors, antitrust issues could arise. However, antitrust concerns are eliminated where: (1) a state board's rule is promulgated under a clearly articulated and affirmatively expressed state policy; and (2) a state board's rule is actively supervised by the State. *N.C. State Bd. of Dental Examiners v. FTC*, 135 S. Ct. 1101, syllabus, 191 L. Ed. 2d 35 (2015); R.C. 107.56(D). In fact, under these circumstances the board is immune from antitrust scrutiny – even if the board is comprised of predominately market participants. *See id.* The proposed rule at issue here falls squarely within this framework.

The Board's proposed rule is promulgated under a clearly articulated and affirmatively expressed state policy. By virtue of its enactment of Chapter 4715 of the Revised Code, it is axiomatic that the Ohio General Assembly clearly articulated and affirmatively expressed as state policy that the Board has authority to regulate dentists and dental hygienists when it created the State Dental Board. The General Assembly clearly articulated and affirmatively expressed as state policy, by the enactment of R.C. 4715.02, that the Board has the duty and authority to create and adopt rules recognizing persons as specialists. In enacting Section 4715.30 of the Revised Code, the General Assembly clearly articulated

and affirmatively expressed as state policy that the Board has the authority and duty to prosecute disciplinary actions against individuals for "advertising services in a false or misleading manner or violating the board's rules governing the time, place, and manner of advertising." Thus, rules promulgated by the Board are done so pursuant to clearly articulated and affirmatively expressed state policy that the Board establish rules governing the manner in which dental professionals may advertise.

The State actively supervises the Board's proposed rule. Here, the Common Sense Initiative Office's current review of the Board's proposed rule is, in fact, the State's active supervision. Thus, if the Common Sense Initiative Office determines the Board's proposed rule is consistent with the clearly articulated and affirmatively expressed state policy of the Ohio General Assembly in enacting Chapter 4715 of the Ohio Revised Code it should approve the Board's proposed rule as required by Section 107.56(E)(1) of the Ohio Revised Code.

The Board's proposed rule is not pretext for self-dealing; rather, it is a logical measure aimed at protecting the health, safety and consumer welfare of Ohioans that is entirely consistent with clearly articulated and affirmatively expressed state policy. The Board's proposed rule sets educational standards for advertising as a specialist. It allows dentists to truthfully advertise other training or certificates, as long as they disclose that the educational provider does not meet the Board's specialty requirements. The consumer can then choose whether he or she wishes to receive treatment from a specialist who meets the Board's requirements (and who might therefore charge a higher fee), or another dentist who is not a recognized specialist, but still has some additional specialty training beyond that of a typical general dentist. Setting educational standards and requiring truthful information for consumers enhances competition by giving consumers relevant information to assist in their decision.

In the healthcare field, regulation is of particular importance. Education and training is a critical factor when choosing a dentist for a procedure and the general public does not necessarily have the knowledge or expertise to distinguish between different types of providers. Thus, it is beneficial for the Board to regulate by establishing educational standards and advertising requirements for the market. Rules such as the advertising rule at issue here are important means by which the Board furthers the State's clearly articulated policy of ensuring that dental services are not advertised in a false or misleading manner.

For these reasons, and the reasons set forth in response to questions 2, 4, 5, 6, 6a, and 9 of the Antitrust Referral Analysis Submitted by the Board – the Board's proposed rule is entirely consistent with state and federal antitrust law and should be approved.

9. What process did the board or commission follow to arrive at its decision to take action/proposed action including public hearings held, public comments invited, studies conducted, data collected interviews conducted, etc.?

The Board created the Ohio Specialties Education Advisory Group (OSEAG), which consisted of the three Board members along with representatives of The Ohio State University College of Dentistry, the American Board of Dental Specialties, the Ohio Dental Association, the American Society of Dentist Anesthesiologists, and the Commission on Dental Accreditation. OSEAG met on July 13, 2017 and voted to refer two options of proposed rule changes to the full Board for consideration.

For purposes of defending against litigation relating to the proposed rule changes, the Board commissioned a survey that was conducted by Measurement Resources Company to study Ohio residents' attitudes and understanding about dental specialist training, certification, and advertising. Additionally, the ODA conducted a separate survey by Saperstein and Associates to study Ohio residents' views regarding dental specialty education, recognition, and advertising. The results of the ODA survey were presented to the Board during its May 9, 2018 meeting.

The Board has also received public input regarding this issue. Counsel for the American Board of Dental Specialties ("ABDS") presented the organization's position to the Board on July 27, 2016. The Board has received written correspondence from interested parties, including the Ohio Society of Oral and Maxillofacial Surgeons, dated May 7, 2018, and the American Association of Orthodontists, dated July 11, 2017 and November 21, 2017.

10. Does the action/ proposed action relate to or depend upon a question that is the subject of a formal opinion request pending before the Ohio Attorney General?

No.

11. Provide any other information the board or commission deems appropriate for the Office's review of the action/proposed action.

The Board is currently being sued in federal district court by the American Academy of Implant Dentistry ("AAID") and two of its member dentists, on the grounds that the Board's advertising rules violate the plaintiff's constitutional rights to freedom of speech, due process, and equal protection. *See American Academy of Implant Dentistry v. Kamdar,* S.D. Ohio Case No. 2:18-cv-00015. Counsel for the plaintiffs has also threatened to bring antitrust claims against the Board members in their individual capacities. The parties agreed to stay the litigation until the completion of the Board's rule review process, and the Board has temporarily suspended enforcement of the challenged rules during the stay. Plaintiffs filed a motion to lift the stay after the Board voted to submit the proposed rule to CSI for review. That motion is pending before the district court.

In addition, the United States Board of Oral Implantology and the International Congress of Oral Implantologists recently filed suit against ABDS and AAID in federal district court in Illinois. *See United States Board of Oral Implantology v. American Bd. of Dental Specialties*, N.D. Ill. No. 1:18-cv-06520. In that case, plaintiffs alleged that ABDS and AAID have made false representations to multiple state boards of dentistry, and have engaged in a conspiracy to suppress competition by encouraging state boards to exclude other certifying organizations from specialty recognition.

*Send this completed form, a complete copy of action or proposed action, and any other documentation deemed appropriate for evaluation to CSIReferrals@governor.ohio.gov.

4715-5-04 Specialty advertising.

(A) A licensed dentist is recognized as a specialist in Ohio if the dentist meets the standards set forth in paragraph (B) of this rule. Any licensed dentist who does not meet the standards set forth in paragraph (B) of this rule is a general dentist. A general dentist is permitted to render specialty services in Ohio.

(B) A licensed dentist must comply with one of the following requirements before being recognized as a specialist in Ohio:

(1) Successfully complete a full-time post-doctoral education program accredited by an accrediting body approved by the United States Department of Education ("USDOE") and provided by an accredited dental college (as defined in R. C. 4715.10), in one of the following specialty areas: dental public health, endodontics, oral and maxillofacial pathology and oral and maxillofacial radiology, oral and maxillofacial surgery, orthodontics and dentofacial orthopedics, pediatric dentistry, periodontics, or prosthodontics; or

(2) Successfully complete a full-time post-doctoral education program accredited by an accrediting body approved by the USDOE and provided by an accredited dental college (as defined in R. C. 4715.10), in an area of general dentistry not listed in subdivision (B)(1) of this rule, including but limited to dental anesthesiology, oral medicine, Implant dentistry, and orofacial pain; or

(3) Successfully complete a full-time post-doctoral education or residency program requiring at least two years of training in an area of general dentistry not listed in subdivision (B)(1) of this rule, including but limited to dental anesthesiology, oral medicine, Implant dentistry, and orofacial pain, and which was completed through an accredited dental college (as defined in R. C. 4715.10), or in a hospital accredited by one of the following entities: The Accreditation Council for Graduate Medical Education (ACGME), The Joint Commission on Accreditation of Healthcare Organizations (JCAHO), The Joint Commission on Accreditation of Hospitals (JCAH), or the Joint Commission; or

(4) The licensed dentist seeking specialty recognition announced their specialty or designation prior to August 1, 1974.

(C) All licensed dentists who advertise services must comport with rules 4715-13-01 to 4715-13-05 of the Administrative Code.

(D) Rules specifically related to the advertising of specialty services are set forth in rule 4715-13-05 of the Administrative Code.

(E) For purposes of this rule, the term "accredited" in relation to a post-doctoral education program means a post-doctoral educational program that is accredited or holds "preliminary provision approval" or "accreditation eligible status" from an accrediting body approved by the USDOE.

4715-13-04 Statements tending to deceive or mislead the public.

All dental advertising, or solicitation, or testimonial endorsement statements which tend to deceive or mislead the public are prohibited.

(A) The following advertising, or solicitation, or testimonial endorsement statements are prohibited:

(1) Statements which falsely indicate the number of years in practice, or the number of years in practice in one location, of any licensee;

(2) Statements which misname any anesthetic, drug formula, material, or medicine, by not accurately stating the generic or brand name of such substances;

(3) Statements which misrepresent the anesthetic, drug formula, material, or medicine, actually administered by a dentist or other qualified licensee;

(4) Statements which misname any dental method or system;

(5) Statements which misrepresent any dental method or dental system actually employed by a dentist or other qualified licensee;

(6) The retention in or about the office or building of a sign or signs of a former dentist, owner, or occupant, for a period longer than ninety days. The owner dentist has ninety days from the date of change in employment to make all necessary changes to signs as necessary and warranted.

(7) Statements on letterhead, business cards, brochures, or other advertisements indicating that a retired, deceased, or other dentist formerly affiliated with the dental practice is still actively practicing dentistry with the dental practice.

(8) Advertisements, announcements, and/or promotions in any form, for dental services, which do not meet the requirements of rule 4715-13-05 of the Ohio Administrative Code.

(B) The state dental board, based on its expertise in regulating the dental profession, has identified certain statements which are likely to mislead the layman who is the target of dental advertising, solicitation, or testimonial endorsements.

4715-13-05 Advertising services as a specialist.

With regard to the advertising of specialty dental services all of the following shall apply:

(A) A dentist who is recognized as a specialist in Ohio must avoid any implication that general dentists associated with him or her in practice are specialists.

(B) The terms specialist, specializes, orthodontist, "oral and maxillofacial surgeon", "oral and maxillofacial radiologist", periodontist, "pediatric dentist", prosthodontist, endodontist, "oral pathologist", "public health dentist", "dental anesthesiologist", "oral medicine specialist", "orofacial pain specialist", "dental implant specialist" or other terms that would cause a reasonable person to believe that a dentist is a recognized specialist, may only be used by a licensed dentist meeting the requirements of paragraph (B) of rule 4715-5-04 of the Administrative Code for the specialty advertised.

(C) A dentist who is not recognized as a specialist under paragraph (B) of rule 4715-5-04 of the Administrative Code may advertise truthful certification, diplomate status or other similar credentials from a bona fide national organization which grants credentials based upon the dentist's postgraduate education, training, and experience, and an examination based upon psychometric principles, if the following disclaimer appears in a reasonably clear and visible manner compared to the announcement of the credential: "[insert name of the organization] does not meet the specialty recognition requirements of the Ohio State Dental Board". Upon request by the board or a member of the public, the licensed dentist must identify the specific training completed and the organization that granted the credential.

(D) A dentist who practices general dentistry and advertises performance of a specialty procedure but is not recognized as a specialist pursuant to Ohio Revised Code 4715-5-04(B) must clearly state in advertising, and/or public promotions, that he or she is a general dentist by stating "General Dentistry" or "General Dentist" in print larger and/or bolder and noticeably more prominent than any other area of practice or service advertised.

(E) Terms referring to areas of practice are permitted, so long as all other provisions of the rules regarding advertising and specialty designation are adhered to.

Effects of the Florida Statutory Disclaimer on Consumers and Providers of Implant Dentistry

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December 11, 2007

Brief Summary

The purpose of the Florida Statutory Disclaimer (FSD) is to help consumers make better decisions. I have examined the effects of the FSD on consumers and providers of implant dentistry. On the basis of evidence from prior research and from a study I commissioned, I conclude that the FSD harms consumer decision making. When compared to people who did not see a disclaimer, more of those who were exposed to the FSD were confused about the situation and more of them recommended a dentist who did not have specific implant dentistry qualifications ahead of a dentist who did. Confusion and inferior recommendations were most common among women and those with less education. The FSD increases costs and leads people to draw false and damaging inferences about dentists who advertise American Academy of Implant Dentistry (AAID) credentials. We did not succeed in an attempt to create a disclaimer that improved comprehension.

Expanded Summary

We conducted experiments using 317 participants selected by mall intercepts in Florida. The participants were shown two mock *Yellow Pages* advertisements for implant dentists and were asked to recommend one of the dentists for a friend who needed implant dental work. In all cases, one of the two dentist advertisements included AAID credentials. The credentials were presented with or without a disclaimer. The disclaimer was either the one required by Florida law or a modified one.

Of those who did not see a disclaimer, 13% recommended a less-qualified practitioner; one who was a DDS but had no apparent qualifications specific to implant dentistry. Among those who saw the FSD, 21% recommended the less-qualified practitioner. Thus, inferior decisions were made by 1.6 times more people when the FSD was used.

Without a disclaimer, those who did not have a college degree were just as likely as those who did to recommend the dentist with credentials specific to implant dentistry. However, when the FSD was used, the percentage of those who recommended the dentist with no apparent credentials was 25% for those without a college degree versus 16% for those with a college degree. In other words, poor decision-making was more than 1.5 times higher among those with less education. Women were also more likely than men to make inferior decisions when they had been exposed to the FSD (28% vs. 15%).

The inferior decisions were partly due to the fact that the FSD led to false conclusions about the AAID. The proportion of participants who thought that the AAID was "not a *bona fide* credentialing organization" was 1.3 times higher when the FSD was included compared to when there was no disclaimer in the advertisement (48% vs. 36%). Confusion affected participants' decisions about which dentist to recommend; those who were confused were nearly 1.8 times as likely (25% vs. 14%) as those who were not confused to recommend the less-qualified dentist.

Prior research shows that disclaimers fail because they are difficult to understand. While they might reduce misunderstanding on certain issues, people have difficulty in using the information in their decision-making. Indeed, the FSD was successful in reducing some misconceptions among some people. However, the gains were modest, and the FSD caused more confusion in other areas; in particular, as noted above, it diminished the AAID and AAID-credentialed dentists in the minds of participants. The net effect was that the consumers seemed to be confused about how to use the information and more of them made inferior decisions.

The FSD also imposes costs on dentists who want to inform prospective patients about their credentials because it increases costs due to greater space requirements for advertisements and it reduces the effectiveness of their advertisements.

We also tested a modified disclaimer. It improved decision-making in comparison with the FSD: only 15% recommended the dentist with no apparent credentials compared to 21% among those who had seen the FSD disclaimer. Nevertheless, the improvement provided by the modified disclaimer was insufficient to match the 13% of inferior decisions among those who had not been exposed to a disclaimer. Moreover, the modified disclaimer caused more confusion than occurred when there was no disclaimer, and it would impose additional advertising costs for credentialed members of the AAID. While further testing might lead to ways of presenting a disclaimer that would neither harm decision-making nor cause confusion, previous research on disclaimers offers little hope in this regard.

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List of Exhibits

Introduction

In this report, I present evidence on the effect of disclaimers in general by drawing upon published research. I then present findings from a study that I commissioned on the effect of the Florida Statutory Disclaimer (FSD) on the consumers and providers of implant dentistry. One of my primary concerns in this report is to assess the extent to which the FSD aids or harms consumer decision making.

Appendix A contains background information.

Prior evidence related to disclaimers

Despite advertisers' efforts to write clearly, people often misunderstand advertisements. Franzen (1994) refers to a 1987 laboratory study of 54 print advertisements in which 1,350 participants were asked to take as long as they wanted to read two advertisements. Their average reading time was 49 seconds. Even with this high level of attention, only 65% of the advertisements were comprehended entirely accurately.

Understanding was found to be better for print advertisements than for the typical magazine article (Jacoby and Hoyer 1989). Nevertheless, Jacoby and Hoyer (1990) estimated that only 70% of a typical print advertisement message is understood. As might be expected, Jacoby, Hoyer and Zimmer (1983) found that comprehension of these advertisements was much better when tested among university students than among the general public.

Confusion is more than twice as high for TV advertisements than for print advertisements according to Jacoby and Hoyer (1990). Schmittlein and Morrison (1983) reanalyzed the Jacoby and Hoyer TV data to correct for the expected proportion of lucky guesses and concluded that only about 46% of the messages were correctly understood.

Disclaimers are particularly difficult to understand. This is due in part to the use of negative words. Jacoby, Nelson and Hoyer (1982) referred to four studies showing that sentences with negative words are difficult to understand. Not surprisingly then, the confusion rates for disclaimers (which are, in essence, negative messages) are expected to be high. Russo et al. (1981) found a median confusion rate of 61% for ten "corrective ads."

Mazis and Adkinson (1976), in a study involving corrective advertising for a mouthwash (Listerine), found that 29% of their 83 subjects misunderstood the message. The effects were the same whether the corrective advertisements were written by the Federal Trade Commission or by the company.

Jacoby, Nelson and Hoyer (1982) examined corrective advertising for Excedrin and Bufferin as worded by the U.S. Federal Trade Commission. Only 24% of their 45 participants understood the message, 40% were confused, and 36% were wrong.

Study on the Florida Statutory Disclaimer

To obtain evidence on the effect of the FSD, I designed a study. I was assisted by Dr. Kesten Green, who is Managing Director of Decision Research Ltd and is a Senior Research Fellow of the Business and Economic Forecasting Unit of Monash University. We commissioned Gallup and Robinson to administer the experiment we designed. Gallup and Robinson and the fieldwork firm employed by them (CRG Global) were not aware of the identity of the client for the research.

We pre-tested the materials in New Zealand using seven people who were United States citizens or who had lived for extended periods in the United States. Minor modifications to the wording of some questions were made as a result of the pre-test interviews (Appendix C).

Participants

Our experiment was designed to assess how people interpret disclaimers and how this affects their choices in a high-involvement decision. As a consequence, the focus of the design was on *how* people think, rather than on *what* they think.

A substantial amount of research has been done using students as subjects. Can one generalize from students to the rest of the world? The answer is "yes" when examining how people think. A meta-analysis of 40 studies on source of communication found that findings from laboratory studies closely match those from field experiments (Wilson & Sherrell 1993). Of particular importance was a study in which Locke (1986) asked researchers to compare findings from laboratory experiments with those from field experiments in 11 areas of human and organizational behavior; the findings were similar.

Although there is not a strong need for a representative sample of participants, we nevertheless decided to conduct the experiments in Florida. In addition, we tried to find participants who were somewhat representative of the broad range of Floridians that might seek information about implant dentistry from the *Yellow Pages*. (The screening questions are provided in Appendix B.) Participation was restricted to those who were over 18 and able to read English.

CRG Global interviewed a total of 317 people face-to-face in malls in Orlando, Daytona Beach, and Fort Lauderdale, between November16 and 28, 2007 (see Appendix B for the fieldwork instructions and materials). The interviews took place in a private area to simulate an unhurried situation. In order to obtain the 317 interviews, CRG Global interviewers approached 1,053 people. A breakdown of the reasons for the early termination of interviews with the 736 people who did not complete interviews is provided in Appendix D. CRG Global reported that there were no problems with the interviewing (Appendix D).

Treatments

Given the large expenditure and significant risk involved, choosing a dentist to perform an implant dentistry operation is a high-involvement decision. In such decisions, consumers and purchasing agents are likely to seek information and to attend closely to advertisements. In order to increase realism and to simulate a high-involvement situation, the participants were asked to suppose they had a friend in need of implant dentistry. They were then presented with two mock *Yellow Pages* advertisements, each on its own card. Each of the advertisements was for a single dentist ("Dr Alan Reed" or "Dr Barry Smith") and they were both headed "IMPLANT DENTISTRY." They both described the advertiser as a "General dentist" and carried the statement, "Implant dentistry is a technique by which artificial replacement teeth are fastened to metal posts surgically implanted in a patient's jaw bones."

This study was designed to obtain evidence on the effects of the FSD on consumers' decisions and on consumers' understanding. To do this, we used six treatments in which Dr Reed's advertisement was provided in one of three variations and both Dr Reed's and Dr Smith's advertisements were either collected or not collected before the participants answered questions about their understanding of the situation.

Dr Reed was described as a Fellow of the AAID and a Diplomate of the ABOI/ID (American Board of Oral Implantology Implant Dentistry). The three variations of Dr Reed's advertisement were (1) no disclaimer; (2) FSD; and (3) modified disclaimer. The "no disclaimer" variation would be illegal under Florida law. The "modified disclaimer" variation was written in order to minimize harm to dentists who advertise AAID credentials while meeting the expressed aims of the Florida legislature. Dr Smith's advertisement listed no qualification other than a DDS and was the same in all treatments.

The advertisements are shown in Exhibit 1.

Exhibit 1: Advertisements used in the study

IMPLANT DENTISTRY

Dr Alan Reed DDS
General Dentist
Fellow, American Academy of Implant Dentistry
Diplomate, American Board of Oral Implantology/Implant Dentistry

Implant dentistry is a technique by which artificial replacement teeth are fastened to metal posts surgically implanted in a patient's jaw bones.

CARD 1

IMPLANT DENTISTRY

Dr Alan Reed DDS
General Dentist
Fellow, American Academy of Implant Dentistry
Diplomate, American Board of Oral Implantology/Implant Dentistry

Implant dentistry is a technique by which artificial replacement teeth are fastened to metal posts surgically implanted in a patient's jaw bones.

Note: Implant dentistry is not recognized as a specialty area by the American Dental Association or the Florida Board of Dentistry. The AAID is not recognized as a bona fide specialty accrediting organization by the American Dental Association or the Florida Board of Dentistry.

CARD 2

IMPLANT DENTISTRY

Dr Alan Reed DDS
General Dentist
Fellow, American Academy of Implant Dentistry
Diplomate, American Board of Oral Implantology/Implant Dentistry

Implant dentistry is a technique by which artificial replacement teeth are fastened to metal posts surgically implanted in a patient's jaw bones.

Note: The American Academy of Implant Dentistry (AAID) provides education, training and testing in implant dentistry. The AAID is the oldest U.S. organization offering credentials in the field. It is independent of the American Dental Association, which does not provide training or certification in implant dentistry.

CARD 3

IMPLANT DENTISTRY

Dr Barry Smith DDS
General Dentist

Implant dentistry is a technique by which artificial replacement teeth are fastened to metal posts surgically implanted in a patient's jaw bones.

CARD 4

After the participants were shown the advertisements, they were asked which of the dentists (Reed or Smith) they would recommend to their friend, using the question, "Q1 Please tell me, which of these dentists would you recommend to your friend?"

In roughly half of the interviews, the interviewer collected the advertisements before asking nine questions designed to reveal participants' understanding about the situation (Appendix B, Q2-10). The numbers of responses that were obtained for each treatment are shown in Exhibit 2.

Exhibit 2: Participants by treatment

Collected ads before questions 2-10?	Dr Reed's (AAID-credentialed dentist) disclaimer			
	None	FSD	Modified	Total
Yes	55	49	51	155
No	57	51	54	162
Totals	112	100	105	317

Participants were next asked which of the two dentists they thought best qualified to do implant dentistry: "Q11 Which of these dentists do you think is better qualified to do implant dentistry?" Question 11 was an alternative way of assessing which of the two dentists participants believed would be the best one to perform implant dentistry on their friend.

Finally, participants were asked a series of demographic questions.

Effects of the Florida Statutory Disclaimer on consumers' decisions

After reading the two mock advertisements, the participants were asked which dentist they would recommend to a friend who needed implant dentistry. When they were presented with an advertisement for an AAID-credentialed dentist that did not include a disclaimer, 13% of participants said that they would recommend the other dentist, who had no apparent qualifications for implant dentistry. Among participants who received the version of the advertisement for an AAID-credentialed dentist that included the FSD, 21% said that they would recommend the dentist without credentials. Thus, the FSD led to 1.6 times as many inferior decisions. (See Exhibit 3.)

The effect of the FSD was greater among those who were less educated and among women. Among those who *did not* see a disclaimer, 12% of participants without a college degree and 13% of those with a degree would recommend the less-qualified dentist. Of those who did see the FSD, 25% of the less-educated participants would recommend the less-qualified dentist, but only 16% of the better educated said they would do so.

Of those who had not seen any disclaimer, the proportions of females and males who recommended the less-qualified dentist were similar to each other at 13% and 14% respectively. However, as shown in Exhibit 3, when given Dr Reed's advertisement with the FSD, 28% of the 46 female participants would recommend the less-qualified dentist, compared with 15% of the 54 male participants.

Exhibit 3: Effects of the FSD on the percentage of participants who recommended the less-qualified dentist

Participant characteristics	No Disclaimer %	FSD %
All participants	13	21
Education		
No college degree	12	25
College degree	13	16
Sex		
Female	13	28
Male	14	15

Because our participants included a substantially higher percentage of college-educated people (Appendix E) and a slightly higher percentage of males than the Florida population, the proportion of potential consumers in the general population making inferior decisions is likely to be higher than it was in our study.

Evidence of confusion

The FSD is intended to reduce confusion among consumers about dentists' claims of expertise. We asked questions designed to assess whether the FSD reduces confusion about the AAID.

Exhibit 4 shows that confusion about aspects of the AAID's credibility was higher among those who had read the FSD than it was among those who had not. In particular, the FSD led more participants to believe that the AAID is not a *bona fide* credentialing organization. Confusion on this matter might harm consumers as well as the AAID.

Exhibit 4: Effect of FSD on confusion over AAID credibility*

Questions	No disclaimer %	FSD %
Recognized as not a *bona fide* credentialing organization [Q6]	60	63
Some accredited members not properly trained [Q7]	55	56
Special training not necessary for good implant dentistry [Q8]	27	28

* confusion = strongly agree + agree + don't know or unsure

People who had received the advertisement with the FSD and were confused were more prone to bad decisions than those who did not receive the FSD but were nonetheless confused. For example, 25% of participants who had received the FSD and who also believed the AAID was not a *bona fide* credentialing organization or who were not sure about this said they would recommend the less-qualified dentist. This compares with only15% of participants who had not seen a disclaimer and who were confused about the AAID as a *bona fide* credentialing organization.

Another misconception is that the American Dental Association would recognize the AAID as an accrediting body. In our study, 93% made this assumption (Exhibit 5). The FSD reduced this confusion from 93% to 68%. At first glance this might look like progress. However, given that they have just been told in the advertisement that this is not so (and indeed half of the participants were still holding the advertisements), the 68% incorrect answers might seem astonishing. Similar results were obtained with respect to questions about other organizational arrangements.

Exhibit 5: Effect of FSD on confusion over organizational arrangements*

Questions	No disclaimer %	FSD %
Recognized as specialty by ADA [Q2]	93	68
Recognized as specialty by FBD [Q3]	83	67
Recognized as an accrediting body by ADA [Q4]	88	64
Recognized as an accrediting body by FDB [Q5]	83	60
Selected organizations recognized by ADA as accrediting bodies [Q9]	89	80
Membership of ADA implies experience in implant dentistry [Q10]	74	64

* confusion = strongly agree + agree + don't know or unsure

How can one explain this modest effect from the disclaimer? People interpret advertisements using their prior beliefs about what is reasonable. Prior beliefs were a key issue for studies in the late 1800s and early 1900s in which people were said to make obvious errors when asked about visual illusions. For example, in the Ponzo illusion, people were shown what looked like a railroad line going off into the distance. Two equal-length lines were imposed horizontally on the tracks and subjects were asked which was longer. They said that the one placed further away on the tracks was longer. (See Wikipedia for a description of this illusion.) The researchers at that time interpreted this as an incorrect response. In fact, people use their prior knowledge when they encounter things in their life. In this case, they saw the tracks as being portrayed in 3-D, so they were actually quite rational in their thinking (Funder 1987). It is unreasonable then, to expect that a disclaimer would be successful in removing a basic misapprehension based on prior knowledge such as, "It seems likely that a large and important organization such as the ADA must be involved in some way".

The more important issue is whether consumers would benefit by having more accurate and complete knowledge about organizational and legal issues relating to the AAID, ADA, and FDB (Florida Dental Board). An extensive body of research indicates that an attempt to educate consumers on side issues would harm decision-making (Armstrong 2007). The reason is that when you have a strong argument (e.g., AAID certification in this case), you should avoid weak arguments; people tend to use an average of the quality of arguments for high-involvement products (Troutman and Shanteau (1976). Someone who is looking for implant dental work would be unlikely to be concerned about such things as how the field is organized just as when people consider purchasing an automobile, say a Ford or Honda car, few of them will be concerned about how the companies are organized. The research findings in this area are summarized by one of the principles in my book, *Persuasive Advertising*, under: "Avoid weak arguments for high-involvement products."

In Armstrong (2007), I summarize evidence showing that for high-involvement products, advertisements should only contain material that is relevant to the consumer's need for information to make a decision about the product. Given that the disclaimer focuses on organizations' details, it is hard to see why it would be relevant to a potential patient or to their purchasing agent. Some people would be confused about whether a disclaimer represents an argument (i.e., a piece of information to aid in making a decision).

One would expect people reading an advertisement to be confused when presented with information that seems irrelevant – even though it may be true information.

Effects of involvement

As noted, the decision to undergo implant dentistry is a high-involvement decision. Under high-involvement, people carefully examine advertisements. To increase feelings of involvement, we had asked participants to play the role of someone advising a friend about dentists who offer implant dentistry.

We also conducted the interviews in locations that offered some privacy so that participants would not feel rushed. In this section, we show the results from two additional ways we used to encourage participants to process the advertisements carefully.

Retaining the advertisements

We allowed half of the participants to retain the advertisements while they answered all the questions. Those participants who retained the advertisement that included the FSD were much more likely to be confused about the AAID's role and standing. Exhibit 6 shows that substantially larger proportions of those who retained the advertisement agreed with or were not sure about three false statements about matters to do with the AAID's credibility.

Exhibit 6: Effect of retaining the advertisement with FSD on confusion about AAID credibility*

Questions	Returned	Retained
	%	%
Recognized as not a *bona fide* credentialing organization	59	67
Some accredited members not properly trained	47	65
Special training not necessary for good implant dentistry	25	31

* confusion = strongly agree + agree + don't know or unsure

Similarly, participants who retained the advertisement that included the FSD were much more likely to be confused about organizational arrangements in the profession. Exhibit 7 shows that greater proportions of those who retained the advertisements agreed with or were not sure about five out of six false statements about organizational arrangements than was the case with those who returned their advertisements.

In other words, the more that people paid attention to the advertisements containing the FDA, the greater their confusion.

Exhibit 7: Effect of retaining the advertisement with FSD on confusion about organizational arrangements*

Questions	Returned	Retained
	%	%
Recognized as specialty by ADA [Q2]	63	73
Recognized as specialty by FBD [Q3]	61	73
Recognized as an accrediting body by ADA [Q4]	61	67
Recognized as an accrediting body by FDB [Q5]	59	61
Selected organizations recognized by ADA as accrediting bodies [Q9]	82	78
Membership of ADA implies experience in implant dentistry [Q10]	55	73

* confusion = strongly agree + agree + don't know or unsure

Retesting after reflection on their understanding

To test whether additional time and examination would reduce confusion, we asked participants a second time to choose between the dentists. This time we asked them which one they thought was the better qualified to do implant dentistry [Q11]. We did this after participants had answered the questions dealing with their understanding of the advertisements.

Among participants who were shown an advertisement for an AAID-credentialed dentist that did not include a disclaimer, 12% recommended the less-qualified dentist. This compares with the 19% of those who received the advertisement that included the FSD who did so. These responses correspond closely to the earlier [Q1] results on recommendations of 13% and 21% respectively.

Among participants who received advertisements that included the FSD, 16% of those who returned the advertisements before answering our questions to assess understanding thought the dentist with no apparent qualifications specific to implant dentistry was the better qualified. In contrast, 22% of those who retained the advertisements made the same assessment.

Effects of a modified disclaimer on consumers' decisions and confusion

We also examined the extent that protection for consumers might be provided by a modified disclaimer. We tested only one possibility. It is shown in Exhibit 8. As can be seen, it suffers from the inclusion of a negative word.

Exhibit 8: Modified Disclaimer

> The American Academy of Implant Dentistry (AAID) provides education, training and testing in implant dentistry. The AAID is the oldest U.S. organization offering credentials in the field. It is independent of the American Dental Association, which does not provide training or certification in implant dentistry.

Consumer decisions

Of those participants given an advertisement including the modified disclaimer, 15% recommended the dentist with no qualifications. This is substantially less than the 21% for those who had received the FSD. However, it is slightly higher than the 13% for those given no disclaimer. Thus, while the modified disclaimer was less harmful to participants' decision making than the FSD, it did not eliminate the harm.

Consumer comprehension

Our modified disclaimer was similar to the FSD in its effect on confusion over the value of AAID qualifications. Among those participants who had received the modified disclaimer, 79% said they thought the AAID dentist was better qualified while 81% of those who received the FSD had thought so. These figures were lower than the 88% of participants who were not exposed to a disclaimer.

The modified disclaimer was not as effective as the FSD at reducing confusion except in one crucial area: when participants were asked about whether or not the AAID is a *bona fide* credentialing organization, confusion was 55% with the modified disclaimer, compared to 60% with no disclaimer, and 63% with the FSD.

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Appendix A: Background

It is the policy of the American Dental Association (ADA) not to recognize as a separate specialty any area of dental practice/dentistry that is included among the activities of specialties that the ADA already recognizes. Implant dentistry is one such area. Three of the specialties already recognized by the ADA (Oral Surgery, Prosthodontics, and Periodontics) have, within the past 12 years, modified the definition of their respective specialty areas to include implant dentistry. It is therefore not possible to obtain recognition for implant dentistry as a separate specialty from the ADA while the Association continues its present policy. Further, the Florida Board of Dentistry (FBD) recognizes as specialty areas only those areas that have been recognized by the ADA.

Implant dentistry may legally be carried out in Florida by any licensed dentist. Florida Statute s.466.0282 requires dentists who wish to advertise their credentials in an area of dental practice not recognized by the FBD to include in their advertisements a disclaimer stating that the area *"(NAME OF ANNOUNCED AREA OF DENTAL PRACTICE) IS NOT RECOGNIZED AS A SPECIATLY AREA BY THE AMERICAN DENTAL ASSOCIATION OR THE FLORIDA BOARD OF DENTISTRY."* A dentist whose advertising mentions a dental organization representing an area of dentistry that is not recognized by the ADA is further obliged to display a statement that the organization in question *"(NAME OF REFERENCED ORGANIZATION) IS NOT RECOGNIZED AS A BONA FIDE SPECIALTY ACCREDITING ORGANIZATION BY THE AMERICAN DENTAL ASSOCIATION OR THE FLORIDA BOARD OF DENTISTRY."*

The American Academy of Implant Dentistry (AAID) and the certifying board it sponsors, the ABOI/ID, offer credentials in implant dentistry. As a consequence of implant dentistry not being recognized as a specialty area of dental practice by either the ADA or the Florida Board of Dentistry and because the AAID does not "condition membership or credentialing of its members upon all" of the criteria listed in 466.0282 (2), dentists in Florida who advertise credentials from the AAID or its certifying board are obliged to include the disclaimer shown here:

> Implant dentistry is not recognized as a specialty area by the American Dental Association or the Florida Board of Dentistry. The American Academy of Implant Dentistry is not recognized as a bona fide specialty accrediting organization by the American Dental Association or the Florida Board of Dentistry.

Appendix B: Materials

A - X

GALLUP & ROBINSON, INC.
PENNINGTON, NEW JERSEY
Job # 8671 – Invitation

BADGE NUMBER: _____ _____ _____ _____ _____

CHECK ONE: Male [ ] Female [ ] ***CHECK SEX QUOTAS***

Good (morning/afternoon). My name is _____. I'm a survey interviewer for Gallup & Robinson, Inc. We are conducting a survey to find people's reactions to advertising. You will not be asked to buy anything. We are only interested in your opinions. Your cooperation would be most valuable.

For this study we are interviewing certain types of men and women. I'd like you to answer a few questions to determine if you are the type of person to be included in this study.

QA We are talking to people of different ages in this study. Which of these groups include your age?
READ LIST AND CHECK ONE.

Under 18	[ ] → *TERMINATE.*	
18 – 34	[ ] → *QB*	
35 – 49	[ ] → *QB*	
50 – 59	[ ] → *QB*	
60 and over	[ ] → *QB*	**CHECK AGE QUOTAS**
DO NOT READ		
DK/NA/Refused	[ ] → *TERMINATE*	

QB Are you, or anyone in your household, currently employed . . . ? ***READ LIST.***

	Yes	No	DK/NA/ Refused
a. In this mall	[ ]	[ ]	[ ]
b. By an advertising agency or marketing research firm	[ ]	[ ]	[ ]

IF RESPONDENT SAYS "YES" OR "DK/NA/REFUSED" TERMINATE AND TALLY. OTHERWISE, CONTINUE TO QC.

QC Do you have any knowledge about the training of dentists and the professional organizations to which they belong?

Yes	[ ] → *TERMINATE*
No	[ ] → *QD*
DK/NA/Refused	[ ] → *TERMINATE*

QD Have you participated in a mall survey within the past six months?

Yes	[ ] → ***TERMINATE***
No	[ ] → ***QE***
DK/NA/Refused	[ ] → ***TERMINATE***

QE Do you wear eyeglasses or contact lenses for reading?

Yes	[ ] → ***QF***
No	[ ] → ***SKIP QF AND CONTINUE***
DK/NA/Refused	[ ] → ***TERMINATE***

QF ***IF "YES" TO QE AND NOT WEARING EYEGLASSES, ASK:*** Do you have your eyeglasses with you, or are you wearing your contacts?

Yes	[ ] → ***CONTINUE***
No	[ ] → ***TERMINATE***
DK/NA/Refused	[ ] → ***TERMINATE***

Your cooperation in this survey would be greatly appreciated and your opinions would be most valuable. It will take approximately 6-7 minutes of your time. Are you willing to participate?

IF RESPONDENT IS WILLING TO PARTICIPATE, BRING HIM/HER INTO A PRIVATE AREA AND CONDUCT THE INTERVIEW. MAKE SURE YOU HAVE THIS SCREENER HANDY WHEN THE INTERVIEW IS COMPLETED. THE SCREENER WILL NEED TO BE INCLUDED WITH THE SURVEY. IF RESPONDENT IS UNWILLING TO PARTICIPATE, THANK HIM/HER FOR HIS/HER TIME.

WRITE NAME OF RESPONDENT: _____

GALLUP & ROBINSON, INC.
PENNINGTON, NEW JERSEY
Job # 8671 – Survey

RECORD TIME STARTED ____ : ____ AM [ ] PM [ ]

This is a survey about implant dentistry. That's a technique in which titanium metal posts are permanently embedded in the patient's jaw in a series of surgical operations, and false teeth are attached to the posts.

Please imagine that you have a friend who needs implant dentistry. You find these two advertisements in the *Yellow Pages*.

Please read these two *Yellow Pages* advertisements carefully.

[FOR "A-X" AND "A-Y"] HAND CARD 1 AND CARD 4 TO RESPONDENT.
[FOR "B-X" AND "B-Y"] HAND CARD 2 AND CARD 4 TO RESPONDENT.
[FOR "C-X" AND "C-Y"] HAND CARD 3 AND CARD 4 TO RESPONDENT.

ONCE RESPONDENT HAS READ BOTH CARDS, ASK:

Q1 Please tell me, which of these dentists would you recommend to your friend?

Dr Reed [ ]
Dr Smith [ ]

[FOR "A-X"] COLLECT CARD 1 AND CARD 4.
[FOR "B-X"] COLLECT CARD 2 AND CARD 4.
[FOR "C-X"] COLLECT CARD 3 AND CARD 4.

[FOR "A-Y"] KEEP CARD 1 AND CARD 4 IN FRONT OF RESPONDENT.
[FOR "B-Y"] KEEP CARD 2 AND CARD 4 IN FRONT OF RESPONDENT.
[FOR "C-Y"] KEEP CARD 3 AND CARD 4 IN FRONT OF RESPONDENT.

HAND RESPONDENT CARD 5 (AGREE/DISAGREE SCALE FOR Q2 TO Q10)

Strongly Agree	Agree	Disagree	Strongly Disagree	Don't know/ Unsure

I'm now going to read you some statements and I'd like you to tell me how much you agree or disagree with each one using *this* scale.

OK, let's get started.

	Strongly Agree	Agree	Disagree	Strongly Disagree	Don't know/ Unsure
Q2 Implant dentistry is recognized as a specialty area by the American Dental Association.	[ ]	[ ]	[ ]	[ ]	[ ]
Q3 Implant dentistry is recognized as a specialty area by the Florida Board of Dentistry.	[ ]	[ ]	[ ]	[ ]	[ ]
Q4 The American Dental Association recognizes the American Academy of Implant Dentistry as an accrediting body.	[ ]	[ ]	[ ]	[ ]	[ ]
Q5 The Florida Board of Dentistry recognizes the American Academy of Implant Dentistry as an accrediting body.	[ ]	[ ]	[ ]	[ ]	[ ]
Q6 The American Academy of Implant Dentistry is not a bona fide credentialing organization.	[ ]	[ ]	[ ]	[ ]	[ ]
Q7 Some accredited members of the American Academy of Implant Dentistry are not properly trained.	[ ]	[ ]	[ ]	[ ]	[ ]
Q8 A dentist doesn't have to be specially trained to be able to do good work in implant dentistry.	[ ]	[ ]	[ ]	[ ]	[ ]
Q9 The American Dental Association recognizes selected organizations as accrediting bodies.	[ ]	[ ]	[ ]	[ ]	[ ]
Q10 Membership in the American Dental Association implies that the dentist has experience in implant dentistry.	[ ]	[ ]	[ ]	[ ]	[ ]

[FOR "A-X"] COLLECT CARD 5. HAND CARD 1 and CARD 4 TO THE RESPONDENT AGAIN.
[FOR "B-X"] COLLECT CARD 5. HAND CARD 2 and CARD 4 TO THE RESPONDENT AGAIN.
[FOR "C-X"] COLLECT CARD 5. HAND CARD 3 and CARD 4 TO THE RESPONDENT AGAIN.

[FOR "-X"] Here are the *Yellow Pages* advertisements you looked at before.

[FOR "-Y"] Please turn your attention back to the *Yellow Pages* advertisements you looked at before.

Q11 Which of these dentists do you think is better qualified to do implant dentistry?

Dr Reed [ ]
Dr Smith [ ]

COLLECT ALL CARDS FROM RESPONDENT.

The following questions are for classification purposes only. Your replies will be held in strict confidence.

Q12 In which year did you last visit a dentist? *IF NECESSARY, SAY: "About what year?"*

2007	[ ]	1996	[ ]	1985	[ ]
2006	[ ]	1995	[ ]	1984	[ ]
2005	[ ]	1994	[ ]	1983	[ ]
2004	[ ]	1993	[ ]	1982	[ ]
2003	[ ]	1992	[ ]	1981	[ ]
2002	[ ]	1991	[ ]	1980	[ ]
2001	[ ]	1990	[ ]	1979	[ ]
2000	[ ]	1989	[ ]	1978	[ ]
1999	[ ]	1988	[ ]	1977 or earlier	[ ]
1998	[ ]	1987	[ ]	Not sure	[ ]
1997	[ ]	1986	[ ]	Never visited a dentist	[ ]

IF RESPONDENT VISITED A DENTIST AT SOME TIME OR NOT SURE, ASK:
Q13 Have you ever had dental implant surgery?

Yes	[ ]
No	[ ]
Not sure	[ ]

IF "YES," TO Q13, ASK
Q14 How old were you when you had dental implant surgery?
ENTER AGE IN BOX BELOW:
IF RESPONDENT IS UNSURE, ENTER "DK"

ASK ALL RESPONDENTS
Q15 Has any close friend or relative ever had dental implant surgery?

Yes	[ ]
No	[ ]
Not sure	[ ]

IF "YES," TO Q15, ASK
Q16 Roughly, how long ago was that?
ENTER NUMBER OF YEARS AGO IN BOX BELOW:
IF RESPONDENT IS UNSURE, ENTER "DK"

HAND RESPONDENT CARD 6 (EDUCATION)

No formal education	High school degree/ GED diploma	2-year College degree	4-year College degree	Masters or Doctoral degree

Q17 What is your highest educational qualification?

No formal qualification	[ ]
High school / GED diploma	[ ]
2-year College degree	[ ]
4-year College degree	[ ]
Master's or Doctoral degree	[ ]
DO NOT READ: DK/NA/Refused	[ ]

COLLECT CARD 6

This concludes our survey. May we please have your name, address and phone number for our records. We are asking for this information only for quality control purposes.

Like all your responses, it only be used for research and will not be sold or shared with other companies or telemarketers.

Respondent's first and last names: _____

Respondent's complete street address: _____

Respondent's city: _____

Respondent's Zip Code (5 digits): _____

Respondent's area code and phone number: _____

Thank you very much for your time and participation.

RECORD TIME COMPLETED _____ : _____ AM [ ] PM [ ]

I HEREBY ATTEST THAT THIS IS A BONA FIDE INTERVIEW, CONDUCTED IN ACCORDANCE WITH MY INSTRUCTIONS.

I personally interviewed the respondent whose name appears in this survey. I was not acquainted with the respondent prior to this interview. I asked the questions exactly as written and recorded the answers exactly as given.

_____ ____ ____ ____ ____ ____

Interviewer's Signature Badge Number

Appendix C: Pre-testing of the materials

Pretest interviews were carried out to ensure that the wording of the questions was not awkward for the interviewers to say, to ensure instructions to interviewers were easy to follow, and to check how easily interviewers could record the answers to questions. The pre-testing was also intended to ensure interviewees were able easily to understand the questions, and to provide an indication of how long individual interviews were likely to last.

Pretest interviews were conducted on Friday 16 November in New Zealand and changes were made that evening.

The pretest interviews were carried out in Palmerston North, New Zealand, a city of about 80,000 people, located some 90 miles north of the capital, Wellington. The interviewer was Don Esslemont, a Director of Decision Research Ltd with 40 years experience in survey research.

Seven people were interviewed. Of the even, six were immigrants from the USA and one was a New Zealander who had been working in California for a number or years and was in New Zealand to attend a family wedding.

Participants were contacted using the method of "snow-balling". Three individuals were contacted directly, and they in turn suggested others for interview. Four out of the seven were faculty members at Massey University.

All of those interviewed had four-year or graduate degrees. Six interviewees were male, one female. Ages ranged from late 20s to late 50s. All were native speakers of English.

Interviews lasted for up to 35 minutes, but much of the time was occupied in discussing participants' understanding of questions. It was estimated that on average it would take no more than about 10 minutes to collect the information in an operational interview.

Version B of the instrument was pretested, using Cards 2 and 4.

In all but one of the interviews, the advertisement "show-cards" were recovered before asking further questions. The one who was allowed to retain the cards studied them carefully while considering his replies, and was clearly basing his answers on a detailed reading of the advertisements.

Findings and changes

Two informants did not grasp the distinctions between implant dentistry and what they called "root canal work". Mentioning titanium posts made it clearer, and the description at the start of the instrument of implant dentistry was therefore altered. The instrument originally had the interviewer saying, "This is a survey about implant dentistry. Implant dentistry is a technique in which false teeth are permanently fastened to the bones in a patient's jaw through a series of surgical operations." This was changed to "This is a survey about implant dentistry. That's a technique in which titanium posts are permanently embedded in the patient's jaw in a series of surgical operations, and false teeth are attached to the posts."

The wording: "Please imagine that you have a friend who needs implant dentistry. You find these two advertisements in the Yellow Pages for dentists who do implant dentistry," was found to be unnecessarily verbose, and the words "for dentists who do implant dentistry" were dropped.

The instruction "HAND RESPONDENT CARD 2 (YELLOW STICKER) and CARD 4 (NO STICKER). ONCE RESPONDENT HAS READ BOTH CARDS, SAY" was simplified to "HAND RESPONDENT CARD 2 and CARD 4". Color coding in the questionnaire (not shown) and on the cards (also not shown) was however implemented in the final materials to make it easier for the interviewers to administer the treatments.

"I'd like you to read these two *Yellow Pages* advertisements carefully AND ASK:" was felt to be clumsy, and was changed to "Please read these two *Yellow Pages* advertisements carefully and tell me". The fieldwork company subsequently made a further change, dropping "... and tell me" and adding the words "Please tell me," at the beginning of Question 1.

The introduction to the questions 2 through 10 originally read: "I'm now going to read you some statements about

implant dentistry and I'd like you to tell me how much you agree or disagree with each statement using the scale on the card I just gave you. Let's start with . . . READ STATEMENT" Some of the wording was found to be unnecessary, and it was simplified to "I'm now going to read you some statements and I'd like you to tell me how much you agree or disagree with each one using this scale HAND RESPONDENT CARD 5".

The introduction to individual Likert scale questions was changed to the fieldwork company's standard wording.

The changes made to the instrument as a result of the pretest are shown below.

B

GALLUP & ROBINSON, INC. PENNINGTON, NEW JERSEY Job # 8671 – Questionnaire

USE THIS QUESTIONNAIRE WITH CARD 2 AND CARD 4

*RECORD TIME STARTED*__ : ____ AM [ ]PM [ ]

This is a survey about implant dentistry. ~~Implant dentistry is a technique in which false teeth are permanently fastened to the bones in a patient's jaw through a series of surgical operations.~~ That's a technique in which titanium posts are permanently embedded in the patient's jaw in a series of surgical operations, and false teeth are attached to the posts.

Please imagine that you have a friend who needs implant dentistry. You find these two advertisements in the Yellow Pages ~~for dentists who do implant dentistry~~.

HAND RESPONDENT CARD 2 ~~(YELLOW STICKER)~~ and CARD 4 ~~(NO STICKER)~~. ~~ONCE RESPONDENT HAS READ BOTH CARDS, SAY~~

~~I'd like you to~~ Please read these two Yellow Pages advertisements carefully and tell me: ~~.AND ASK:~~

Q1 Which of these dentists would you recommend to your friend?

Dr. Reed [ ]

Dr. Smith [ ]

COLLECT CARDS 2 AND 4 ~~AND HAND RESPONDENT CARD 5 (AGREE/DISAGREE SCALE)~~

Q2 **I'm now going to read you some statements ~~about implant dentistry~~ and I'd like you to tell me how much you agree or disagree with each ~~statement~~ one using ~~the~~ this scale ~~on the card I just gave you. Let's start with . . . READ STATEMENT~~.** HAND RESPONDENT CARD 5.

~~Do you "strongly agree," "agree," "disagree," "strongly disagree," or are you "not sure" that . . .~~ How far do you agree or disagree with this statement: READ STATEMENTS AND RECORD ANSWERS ~~AGAIN~~.

	Strongly Agree	Agree	Disagree	Strongly Disagree	Not Sure
a. Implant dentistry is recognized as a specialty area by the American Dental Association.	[ ]	[ ]	[ ]	[ ]	[ ]
b. Implant dentistry is recognized as a specialty area by the Florida Board of Dentistry.	[ ]	[ ]	[ ]	[ ]	[ ]
c. The American Dental Association recognizes the American Academy of Implant Dentistry as an accrediting body.	[ ]	[ ]	[ ]	[ ]	[ ]
d. The Florida Board of Dentistry recognizes the American Academy of Implant Dentistry as an accrediting body.	[ ]	[ ]	[ ]	[ ]	[ ]

e.	The American Academy of Implant Dentistry is not a bona fide credentialing organization	[ ]	[ ]	[ ]	[ ]	[ ]
f.	Some accredited members of the American Academy of Implant Dentistry are not properly trained.	[ ]	[ ]	[ ]	[ ]	[ ]
g.	A dentist doesn't have to be specially trained to be able to do good work in Implant dentistry.	[ ]	[ ]	[ ]	[ ]	[ ]
h.	The American Dental Association recognizes selected organizations as accrediting bodies.	[ ]	[ ]	[ ]	[ ]	[ ]
i.	Membership in the American Dental Association implies that the dentist has experience in implant dentistry.	[ ]	[ ]	[ ]	[ ]	[ ]

COLLECT CARD 5. HAND CARD 2 and CARD 4 TO THE RESPONDENT AGAIN.

Please look at ~~the same Yellow Pages advertisements you looked at before~~ these advertisements again.

Q3 Which of these dentists do you think is ~~best~~ better qualified to do implant dentistry?

Dr. Reed [ ]

Dr. Smith [ ]

COLLECT ALL CARDS

The following questions are for classification purposes only. Your replies will be held in strict confidence.

Q4 In which year did you last visit a dentist? **IF NECESSARY SAY**: "About what year" [_____] Not sure [ ]

Has never visited a dentist [ ]

IF RESPONDENT VISITED A DENTIST AT SOME TIME OR NOT SURE, ASK:

Q5 Have you ever had dental implant surgery?

Yes [ ]

No [ ]

Not sure [ ]

IF "YES," TO Q5, ASK

Q6 How old were you when you had dental implant surgery? [____] years old Not sure [ ]

ASK ALL RESPONDENTS

Q7 Has any close friend or relative ever had dental implant surgery?

Yes [ ]

No [ ]

Not sure [ ]

IF "YES," TO Q7, ASK

Q8 Roughly, how long ago was that? [____] years ago Not sure [ ]

HAND RESPONDENT CARD 6

No formal education	High school degree/GED diploma	2-year College degree	4-year College degree	Masters or Doctoral degree

Q10 What is the highest educational degree you have?

No formal education	[ ]
High school degree/GED diploma	[ ]
2-year College degree	[ ]
4-year College degree	[ ]
Masters' or Doctoral degree	[ ]

This concludes our survey. Thank you very much for your time and participation.

Appendix D: Fieldwork

The field work was conducted by CRG, under the guidance of Gallup and Robinson (G&R). All communications with the fieldwork company was conducted through G&R. Neither G&R nor CRG knew the identity of the ultimate client for the research.

CRG has its offices in Florida at:

CRG Global, Inc.
3 Signal Avenue – Suite A
Ormond Beach, FL 32174
www.CRGGlobalInc.com

CRG Global Inc. adheres to the Marketing Research Association code of ethics and standards in their interviewing practices. CRG Global Inc. is a Member of the Marketing Research Association (MRA), American Marketing Association (AMA) and certified by WBENC (Women's Business Enterprise National Council). It has been in business since the early 80s.

CRG Global Inc. executed the Dental Implant survey using Cunningham Field and Research Services. Cunningham Field and Research operates out of 30 malls nationwide, three of which are in Florida. They used all three for the study:

1. Florida Mall in Orlando FL
2. Pembroke Lakes Mall in Ft. Lauderdale/Miami, FL
3. Volusia Mall in Daytona Beach, FL

All employees were fully briefed for a minimum of 45 minutes to an hour. Practice interviews are always done, and were done for this study before it began.

The average length of employment at CRG Global is approximately 7 years (supervisors) and 2-3 years (interviewing staff) across the three specific Florida malls for this study. When hired, all new employees go through a minimum training period ranging from 2-6 weeks depending on the position they are being hired to fill.

The table below provides a breakdown of the people who were approached for an interview, but were not interviewed because they were not eligible or refused.

Reason for termination	Number terminated
Initial refusal	571
Under 18	80
Past participation	40
Refused by eligible respondent	28
Employment	9
Knowledge about dental training	7
No eyewear	1
Total terminated	736

CRG report

The CRG locations started the project on the 16th and ended the project on the 29th. All staff were fully briefed and supervisors monitored the progress during the course of the study. We felt there were limited issues in the locations. As reported there were a few issues with our interviewers incorrectly inputting the respondent names instead of their own because the program asked for the "pledge" name but those issues were corrected and where we could not correct we replaced. The study seemed to complete and fall in line with the information provided to us during bidding.
Lee Apperson, Project Manager
CRG GLOBAL, INC.

Appendix E: Education of participants and Florida 2006 population [1]

	College degree
Florida 2006 population estimate	25%
Participants	54%
Ratio of participants / population	2.17

[1] From http://www.census.gov/population/www/socdemo/education/cps2006.html adjusted for age bands using US population data ratios of college degree holders.

Evidence on the effects of mandatory disclaimers in advertising

Green, Kesten C. and Armstrong, J. Scott

University of South Australia, University of Pennsylvania

30 March 2012

Evidence on the Effects of Mandatory Disclaimers in Advertising
With reply to commentators:
Should We Put a Price on Free Speech?

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Abstract

We found no evidence that consumers benefit from government-mandated disclaimers in advertising. Experiments and common experience show that admonishments to change or avoid behaviors often have effects opposite to those intended. We found 18 experimental studies that provided evidence relevant to mandatory disclaimers. Mandated messages increased confusion in all, and were ineffective or harmful in the 15 studies that examined perceptions, attitudes, or decisions. We conducted an experiment on the effects of a government-mandated disclaimer for a Florida court case. Two advertisements for dentists offering implant dentistry were shown to 317 subjects. One advertiser had implant dentistry credentials. Subjects exposed to the disclaimer more often recommended the advertiser who lacked credentials. Women and less-educated subjects were particularly prone to this error. In addition, subjects drew false and damaging inferences about the credentialed dentist.

Key words: consumer protection; corrective advertising; decision making; government regulation; judgment.

Sellers often provide disclaimers in order to inform customers about their products and to avoid lawsuits. Lawmakers and regulators nevertheless sometimes[1] impose disclaimers when they believe that sellers would otherwise fail to inform buyers. Mandatory disclaimers are government-required messages that have the form: Product-X is [not] Y.

In this paper, we scrutinize the rationale for such restrictions on speech, examine the legal history of disclaimers in the U.S., and review the prior experimental evidence on the costs and benefits of disclaimers. We then describe an experiment that we conducted for a court case about a disclaimer mandated by the government of Florida.

Economic Rationale for Restrictions on Commercial Speech

The argument for mandatory disclaimers is inconsistent with economic principles and knowledge of the roles of sellers, regulators (who sometimes stand between sellers and buyers), and buyers, as we describe below[2].

Sellers

It is in sellers' economic interests to treat customers well and, especially, to avoid misleading them. They are motivated to tell consumers about the limitations of their products in order to develop good long-term relationships with them, and to avoid the costs of dealing with disgruntled customers and with lawsuits. Unsurprisingly, then, sellers have long used disclaimers in advertising. Research on advertisements that tell the bad along with the good has found that they are persuasive when the negative features are important to consumers (Armstrong 2010, pp. 124-126).

Sellers are motivated to provide warnings with products that may be dangerous in surprising ways or extents, for example with a clear liquid that is poisonous, but not with a knife. Warnings are usually helpful. In a meta-analysis involving 12 experiments and 3 quasi-experiments involving 79 comparisons, Cox *et al.* (1997) found the warnings yielded an average gain in compliance of 15.7% compared to having no warning. However, in one-third of the comparisons, the presence of a warning had no effect, or reduced safe behavior.

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[1] Ben-Shahar and Schneider (2011) documented the "spectacular prevalence" (p. 647) of mandated disclosures.
[2] For a review of the aspects of the economics of information that are relevant to buyer and seller behavior, see Calfee and Ford (1988).

Sellers are also motivated to provide benefits to potential customers, and to tell them about those benefits, if they are free to do so. Consider the following examples:

- Breakfast cereal companies increased fiber content and introduced advertising of the benefits of fiber when restrictions on advertising health benefits were lifted. Consumers increased their consumption of high-fiber cereals (Ippolito and Mathios 1991).
- Women reduced their consumption of saturated fats within the fats and oils category by 24% in the five years after advertising restrictions were lifted in 1985, a substantially more rapid change than occurred during the preceding eight years (Ippolito and Mathios 1995).
- Cigarette companies reduced tar and nicotine levels after the Federal Trade Commission's prohibition of comparative health claims in cigarette advertisements was lifted (Craswell 1991).
- Prior to mandatory nutrition labeling, sellers were motivated to tell consumers about features of their products that were considered to have health advantages. When a new mandatory labeling regime that restricted claims that sellers could make was instituted, the share of healthier cooking oils sold decreased (Mathios 1998).

Buyers

People are accustomed to dealing with biased information in all areas of life, including when making decisions as consumers. When they are not expert in a product category, consumers tend to seek out independent information, use trusted suppliers, or buy well-known brands. If customers discover they have been misled after they have purchased a product, they are likely to avoid purchasing the product in the future, demand a refund, tell others not to buy it, post comments on the Internet, or sue.

Consumers are also aware from experience and from knowledge of human nature that government officials are fallible, sometimes biased, and sometimes duplicitous in the information they provide. In addition, people often attribute higher benefits to products they are told they cannot have.[3] As a consequence, consumers may fail to respond to government-mandated messages in the ways that the regulators intend them to.

Regulators

While sellers in free markets are motivated to look after buyers, there will likely be some sellers who deliberately mislead consumers in the hope of short-term profits. Such exceptions to normal market behavior are proposed as a key rationale for regulation. Market regulators, however, face a complex problem. They must devise, implement, and enforce regulations that increase welfare beyond that which is achieved by many individual buyers and sellers—each with different information, preferences, situations, and tradeoffs—who are engaged in many voluntary transactions. And they must do so without violating the property and other rights of citizens.

Even with the best of intentions, the available evidence suggests that it may not be possible to increase welfare by government regulation or information policies (see, e.g., Winston 2006, 2008 for reviews of the evidence).

In practice, the regulatory philosophy adopted by governments may not be one of welfare maximization and may vary, thereby increasing uncertainty for sellers and confusion for buyers (Eggers and Fischhoff 2004). Regulators may also fail to implement the wishes of elected legislators, as Emord (2000) described in relation to the Food and Drug Administration's (FDA's) "arbitrary and capricious" and "virtually unbridled discretion over commercial speech" (p. 139) restrictions on health claims about products[4].

Government officials and judges face neither the direct accountability of a seller, nor the search costs and pleasure or regret of a buyer. Instead, they face the temptation to impose their own beliefs on others, and lobbying from sellers—who would like to restrict their competitors' ability to communicate benefits—and from organizations with agendas hostile to the seller.

The following examples suggest that regulators' understanding of these complex situations may never in practice be sufficient to ensure that regulations increase welfare.

In 1980, the FDA issued a warning that pregnant women should avoid coffee due to a risk of birth defects (Burros 1982). In 1981, researchers claimed coffee was responsible for half of all pancreatic cancers. Both claims of harm from coffee consumption were later reversed; the pancreatic cancer claim was reversed by the original researchers. (Simon, 1996, summarized three studies on this issue.) Researchers later claimed that coffee has net health benefits (e.g., Larsson and Orsini 2011).

The U.K. Food Safety Act of 1990 effectively outlawed the use of wooden chopping boards and utensils in commercial kitchens in the belief that they were unhygienic. The belief was based on a study that involved the cultivation of scrapings from wooden working surfaces taken from 211 butchers' shops and 24 restaurants in London. The researchers found that 4% of the cultivated samples contained salmonellae (Gilbert and Watson 1971). Government inspectors vigorously enforced the rule causing much disruption and upset. Subsequent experimental research in 1993 designed to more realistically

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[3] For evidence on this "scarcity principle," see Armstrong 2010, pp.71-74.

[4] "In particular, Congress condemned the FDA's long delay (until 1996) in authorizing a health claim that associated folic acid with a reduction in the risk of neural tube defects (a claim endorsed by the Centers for Disease Control and Prevention in recommendations to the U.S. public in September of 1992), placing blame for preventable neural tube defect births between 1992 and 1996 squarely on the agency" (Emord 2000, p. 140).

replicate conditions in kitchens found that wooden boards have antibacterial qualities, killing 99.9% of bacteria within three minutes, whereas bacteria persisted on the replacement plastic boards. The ban was reversed that year (Booker and North 2007).

The user of a drug developed serious side effects and sued the manufacturer for damages claiming the manufacturer knew about mounting evidence of the generic drug's dangers but did not warn consumers. The manufacturer maintained that the company was bound to stick with the mandated labeling. The Supreme Court found in *Pliva, Inc. v. Mensing* (2011) that pharmaceutical manufacturers could not be held liable under state tort law for insufficiently warning consumers because changing the warning would have breached the Federal warning label mandate.

In a review of government information policies, Winston looked at three situations that had been proposed in 2007 as examples of mandatory disclosure policies that increased welfare: Financial disclosure, mortgage lending, and restaurant hygiene. He found no evidence that the mandated disclosures improved the situations for consumers, or that there were problems in the first place. He concluded, "empirical evidence does not persuasively indicate that any information policy has been effective" (p. 174) and proposed benign neglect as the appropriate response by policy makers to alleged information problems (Winston 2008.)

Economic theory, then, suggests that in free markets sellers are motivated to treat customers well in order to make a profit, buyers are motivated to exercise caution, and welfare tends to be maximized. In regulated markets, sellers are restricted in their ability to serve customers, buyers are less cautious, and regulators face temptations, lack knowledge and, in practice, lack the incentive to obtain useful scientific knowledge on the effects of proposed regulations.

Evidence on Human Behavior Relevant to Mandated Disclaimers

By mandating disclaimers, governments absolve buyers and sellers of responsibility for care and thereby encourage irresponsibility. The presence of a government mandated message suggests that an authority has carefully reviewed the product. The authority of a government mandated message or product feature might reassure consumers that that they are being looked after, causing them to become less vigilant. For example, a study involving 1,307 Washington State drivers and 6,234 observations of their annual accident frequency from 1992 through 1996 found that drivers who purchased cars with airbags and anti-lock brakes drove more aggressively to the extent that the safety benefits were much less than expected (Winston, Maheshri, and Mannering 2006). This type of response is referred to as the risk compensation hypothesis or offset hypothesis in the economics literature.

Consider, now, the effect of a sign posted by the U.S. National Park Service intended to discourage the theft of petrified wood. When the sign was in place, the theft rate was nearly three times higher than when it was not[5]. Why? The sign was a signal to park visitors who would otherwise not have stolen that stealing the petrified wood was a common behavior: In this case, the social proof that fellow visitors stole wood more than outweighed the admonishment from an authority not to steal (Cialdini 2003).

Government-mandated messages often have the purpose of changing or discouraging specific behaviors, for example to stop smoking or to avoid overconsumption of alcohol. Experimental research on persuasion has shown that it is hard to change or to prevent behavior. (This is also the common experience of people with teenage children and spouses.) Mark Twain (1885) recognized that restrictions can make a product *more* attractive to potential consumers when his character, "The Duke," wrote an advertising bill including the lines "For 3 Nights Only!" and "LADIES AND CHILDREN NOT ADMITTED," and then said in reference to the latter "There, if that line don't fetch them, I don't know Arkansaw."

Twain's insight is consistent with the evidence on resistance to persuasion summarized in Armstrong (2010). When consumers are told that they should not or may not do something that they are currently free to do, their desire to engage in the behavior increases. For example, when Miami prohibited the sale, possession, and use of laundry detergents containing phosphates, the regulation induced an artificial scarcity and resentment over the loss of freedom to choose. Consumers responded by increasing their ratings of the effectiveness of phosphates in detergent (Mazis 1975). In another example sixty-four subjects in a laboratory experiment were provided with statements that were said to be from a pornographic book. Half of the subjects were also told that the book was restricted "to those 21 and over." This substantially increased their desire to read the book (Zellinger *et al.* 1975). The phenomenon is widely observed and heavily researched, and is referred to elsewhere in the literature as reactance (Ringold 2002).

Disclaimers sometimes conflict with current behaviors or attitudes, as when consumers are informed of dangerous side effects from smoking. When people are exposed to information that challenges their beliefs or behavior, instead of changing they often react defensively by strengthening their current beliefs. Moreover, contrary to intuition but consistent with evidence from cognitive dissonance studies, when people believe that disconfirming evidence is valid they tend to reinforce their prior beliefs more fervently (see, e.g., Batson 1975).

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[5] Cialdini (2003) cites a theft rate of 7.92% when a sign with a "descriptive-norm" message was present, and of "just under 3%" (his Endnote 2) when no sign was present.

In a related phenomenon, advertisers sometimes use two-sided arguments. They tell about the advantages in order to create positive beliefs about their product and then describe problems, as in the car has extraordinary performance but it is only available in manual and changing gears requires skill. This increases the believability of their advertisements. Customers exposed to a government mandated message might think, "Sure this product has negative aspects, but now that the government has told me what they are I don't have to worry that there might be some really bad problems that I don't know about."

Weak counter arguments are effective at increasing demand when potential consumers are cognitive misers and engage in relatively little effort to process an advertisement. In four experiments involving 555 subjects, the subjects initial positive assessments of products were strengthened when they were exposed to weak negative information (Ein-Gar, Shiv, and Tormala 2012).

Often, mandated disclaimers are irrelevant to consumers and so their presence can distract consumers from product information that is important to them (Osterhouse and Brock 1970). Distracted consumers make inferior decisions.

Much research has been done on how to improve readership and the evidence has been summarized in the form of principles (Armstrong 2010). For effective communication of information, message text should be large enough so that even those with reduced vision can read it, be placed on a white background in columns and in a standard serif typeface. While presenting text all in capitals and a bold sans-serif typeface might intuitively seem likely to emphasize a message, it actually reduces readability and readership. Thus, disclaimers are commonly presented in ways that violate the principles and thereby discourage readership. For audio advertisements, disclaimers are presented using fast talkers, which sounds authoritative and saves on media costs, but is also not effective for conveying information.

The drafters of disclaimers, whether sellers or regulators, are at a disadvantage: Negative arguments and words are more difficult to understand than positive ones.

Disclaimers increase the amount of text in an advertisement. Interestingly, there is evidence that advertisements with more text are regarded as more believable—as in "long copy sells"—even when there is no time to read it (Meyer-Hentschel 1984). Thus, by its mere presence, a disclaimer might encourage greater consumption of the product (such as taking a drug) that the disclaimer is intended to discourage the use of.

In summary, attempts to change behavior using mandatory disclaimers are often ineffective and in many cases lead to effects that are opposite to those intended. When the government takes more responsibility, citizens take less. Most of us do not like being *told* what to do, and may rebel. We cannot justify devoting our time to details that will not affect our decisions and we struggle to understand disclaimers when we do give them our time. [6]

Legal Basis for Commercial Speech Restrictions

"Congress shall make no law…abridging the freedom of speech…"

Our reading of the First Amendment to the U.S. Constitution suggests that it establishes an unconditional right to free speech: The right to choose for oneself what to say, and what not to say. When, in 1731, Benjamin Franklin wrote an editorial regarding his publication of a sea captain's advertisement containing a note that offended some of his readers[7], he made no "commercial speech" distinction in his defense of free speech. The First Amendment apparently applied without restrictions until the late 1920s.

Thierer (2011) argued that it is not possible to make a clear distinction between commercial and other speech. Indeed, the Supreme Court examined the difficulty of properly drawing such a distinction in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council* (1976). In their opinion in favor of prescription drug consumers who challenged a statute that prevented pharmacists from advertising prices, the Justices stated, "we see no satisfactory distinction between the two kinds of speech… As to the particular consumer's interest in the free flow of commercial information, that interest may be as keen, if not keener by far, than his interest in the day's most urgent political debate."

The Supreme Court has, nevertheless, created a commercial speech distinction and has ruled that such speech has lesser First Amendment protection and can therefore be regulated. Our review of the legal basis for commercial speech regulations (see Appendix) led us to conclude that government and the courts justify regulations on the assumption that they protect consumers from making bad decisions. To our knowledge, there is no evidence to support that assumption, a conclusion that was also reached in a review of mandated disclosures (Ben-Shahar and Schneider 2011).

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[6] A California court case involving a mandatory disclaimer ended abruptly on October 15, 2010, a day before one of us was scheduled to testify, when the judge granted a request for a directed verdict after the State had rested its case. The lawyers making the request pointed out to the judge that the State had not met its burden of justifying the mandatory disclaimer and that the survey experts for the State of California had misinterpreted the disclaimer in the research that they had done to support its use. The case had been going on for 7 years (*Michael Potts and AAID v. Brian Stiger, et al. 2010).*

[7] The captain's note stated, using colloquial language, that he would not provide passage on his ship to prostitutes or ministers of the Church of England under any circumstances.

U.S. Supreme Court Justices Thomas and Ginsburg issued a dissenting opinion when the Court decided not to hear a mandatory disclaimer case (*Borgner et al. v. Florida Board of Dentistry et al.* 2002). The dissenting Justices stated, "If the disclaimer creates confusion, rather than eliminating it, the only possible constitutional justification for this speech regulation is defeated." The Justices said that the case presented "an excellent opportunity to clarify some oft-recurring issues in the First Amendment treatment of commercial speech and to provide... guidance on the subject of state-mandated disclaimers" including clarification of "the nature and the quality of the evidence a State must present to show that [a disclaimer] directly advances the governmental interest asserted."

We suggest that, in order to obtain proper evidence, it is *necessary* to conduct experiments in order to predict the effects for each and every restriction proposed. Situations change, so it would be necessary to conduct further experiments over time to determine whether a net benefit still existed.

Prior Evidence on Government-Mandated Messages

We examine the issue of mandatory messages by looking first at whether they reduce confusion and then examine whether they have beneficial outcomes. To address these issues, we relied on empirical, especially experimental evidence. For complex situations such as this, findings from non-experimental studies are unreliable (Armstrong 2010, pp. 7–10).[8] By examining experimental evidence on the effects of mandatory disclaimers, we treat the issue as a subject for scientific investigation rather than as a matter for voting or expert opinion. To the best of our knowledge, this is the first comprehensive review of the evidence on mandatory disclaimers.

Our primary criterion for including a study was that it employed an experimental or a quasi-experimental design to compare the effects of using a disclaimer versus not using one. We considered any fully disclosed study, regardless of whether or not it was published in an academic journal.

We conducted Google Scholar, ISI, and JSTOR searches for articles or legal opinions that contained the terms "experiment" and "mandatory disclaimers," "corrective advertising" and related terms. We also examined papers that cited key papers such as the review of corrective advertising by Wilkie, McNeill, and Mazis (1984). We also posted our working paper on the Internet for many months and sought comments widely.

Our most successful search efforts involved contacting legal scholars and leading researchers on the topic, and checking references from key studies.

To ensure that our summaries of the studies were accurate, we sent our paper to the authors. Their replies led to many corrections.[9] We also asked the authors whether we had overlooked evidence. Their responses helped us to find relevant experiments.

Government-Mandated Messages Cause Confusion

Consumers often fail to understand government-mandated messages. For example, in an experiment on corrective advertising, 83 subjects heard one of four versions of a Listerine mouthwash advertisement. Two of the four versions of the advertisement included a U.S. Federal Trade Commission mandated disclaimer. Of the responses from the 36 subjects who recalled a disclaimer after prompting, 39% misperceived the disclaimer in ways that harmed their assessments of aspects of the brand that were not addressed by the disclaimer (Mazis and Adkinson 1976).

Lawyers for the Federal Trade Commission proposed two sets of three corrective advertising messages for the pain relief drugs Excedrin and Bufferin. To test understanding of the messages, 451 subjects were given questionnaires for at least two of the proposed statements. The proposed statements were each followed by ten choices: One or two correct interpretations of the proposed statement, six or seven misinterpretations of the proposed statement, a "none of the above" response, and a "don't know" response. Only 24% of choices made by the subjects were correct interpretations of a proposed statement (Jacoby, Nelson, and Hoyer 1982, p. 63). One reason for the result is that disclaimers typically use negative words, and statements with negative words are difficult to understand (Armstrong 2010, p. 185–6).

Berlex Laboratories, Inc. (part of Schering-Plough Corporation) had been ordered to provide a disclaimer stating that it had no relationship with another company, Schering AG. The disclaimer said that, "Schering AG, West Germany, is not connected with Schering-Plough Corporation or Schering Corporation, Kenilworth, New Jersey." An advertisement with the disclaimer was compared to one with no disclaimer, as well as to one that had a "claimer" saying the companies *were* related. The 600 physician and pharmacist subjects were given as much time as they wanted, and they responded to questions immediately after they had reviewed the advertisements. The disclaimer reduced the incorrect responses from 58% to 46%. However, and surprisingly, the percentage of people who thought the companies were related was *lower* for the claimer than the disclaimer (Jacoby and Szybillo 1994).

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[8] This problem is not unique to advertising. It has been found in other fields, such as epidemiology, where researchers and officials are often misled by analyses of non-experimental data (Kabat 2008).

[9] Wright and Armstrong (2008) found that academic papers often improperly summarize findings from published research, partly because the authors had failed to read the papers they cited.

Government-Mandated Messages Have Unintended Effects on Beliefs and Behavior

FTC policy requires that remedies should correct consumers' misperceptions, but not harm their evaluations of firms. This does not appear to be the case in practice, however, as the following two examples show. When 58 subjects viewed a corrective advertisement about one of a firm's products, they reduced their ratings of unrelated products made by that firm (Johar 1996). Similarly, in a series of five experiments, a total of 961 subjects exposed to an advertisement that included a correction were less persuaded by subsequent advertising for a different product by the same firm and by an unrelated firm selling a similar product (Darke, Ashworth, and Ritchie 2008).

In a lab experiment 64 subjects read "original" and "acceptable" advertisements for Firestone tires, Listerine mouthwash, Freihofer's bread, and Crown petroleum. The original advertisements were ones that had been judged to be deceptive in Federal Trade Commission (FTC) proceedings. The acceptable advertisements were ones that had been modified from the original using FTC guidelines by either eliminating or qualifying offending content. Despite the drafters' intentions, the "acceptable" alternative advertisements had similar effects on subjects' beliefs as the original advertisements. The lack of effect is not surprising in the light of the fact that none of the product attributes of concern to the FTC were considered relevant to purchase decisions by 30 raters (Glassman and Pieper 1980).

How should patients react if they are informed that their doctor has a conflict of interest in recommending a treatment? In two experiments involving 1,704 subjects in the role of patient, the "patients" who were exposed to a required disclosure were less inclined to trust their doctor, to accept the recommended treatment, and to see the doctor in future, but they worried that the doctor would believe they thought he was biased if they turned down his recommendation (Sah, Loewenstein, and Cain 2011).

In a field experiment, approximately 200 male high school students who were exposed to warning signs stating "DANGER, Shallow Water, You Can Be Paralyzed, NO DIVING," were found to be more likely to dive into the shallow end of the pool than were the similar number of students who were not exposed to the sign (DeTurck and Goldhaber 1991).

In a laboratory experiment, 155 subjects exposed to an advertisement (picture of a bottle or can of alcoholic beverage with label) with the U.S. Surgeon General's warning displayed underneath, rated benefits as greater and risks as lower than subjects who were given the advertisement without the warning. In addition, male subjects exposed to the warning reported higher drinking intentions than those who were not (Snyder and Blood 1992, with a successful replication and extension by Blood and Snyder 1993).

In another laboratory experiment, brief descriptions of 12 made-for-television films were provided to 360 subjects, Subjects exposed to warnings that a film contained violent content more often chose a violent film than did subjects who were not exposed to warnings (Bushman and Stack 1996).

In a test of the effect of a warning from the Surgeon General about the relationship between fat consumption and heart disease, subjects were given a choice between full-, reduced-, and no-fat cream cheese. The 120 subjects who were exposed to labels that included information on fat content and the warning were more likely to want to taste the full-fat cheese than the other cheeses. The pattern was similar for the 120 subjects who were not exposed to the information and warning, but 120 subjects who were exposed only to the information on fat content were more likely to want to taste the lower fat, allegedly healthier, cheeses. When asked to choose one of the cheeses to taste, the subjects were no more likely to taste the lower fat cheeses when they were exposed to the Surgeon General warnings than when they were exposed only to the information (Bushman 1998).

Three laboratory experiments involving the consumption of regular or low-fat M&Ms found that when foods were labeled as low fat, consumers, especially overweight consumers, ate up to 50% more (Wansink and Chandon 2006). One possible explanation is that they felt less responsible for their own health.

An experiment on perceptions about a fictitious new energy supplement among 78 current dietary supplement users tested the effects of a warning ("Caution: Taking more than the recommended serving may result in side effects such as high blood pressure, heart attack, or stroke") and a disclaimer ("This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease"). Subjects exposed to the warning saw the product as less safe but more effective than did those who where not exposed to the warning. Subjects exposed to the mandatory disclaimer did not perceive the product any differently from those who were not exposed to the disclaimer. A second study, involving a diet supplement and 199 subjects, led to the same finding: the warning was effective in changing perceptions in the intended direction, but the mandated disclaimer was not. Indeed, among subjects who were dietary supplement users, exposure to the disclaimer *improved* perceptions of the product (Mason, Scammon and Fang 2007).

To test the effect of a mandatory disclaimer, 1,471 randomly selected U.S. residents were shown football jerseys during an interview in their homes. The respondents were shown five jerseys either with or without a disclaimer, and were later shown a National Football League authorized jersey for comparison. The disclaimer read, "Not authorized or sponsored by the N.F.L.". The disclaimer had no meaningful effect on confusion, quality perceptions, or purchase preferences (Jacoby and Raskopf 1986). The authors suggested that this was consistent with behavioral research on information processing and the use of negative words.

In two experiments, a total of 146 subjects were briefly shown claims about health and medical matters on a computer screen. Claims described as false were later incorrectly remembered as true. Repetition of the disclaimer inflated

this false conclusion after three days. Older adults were more prone to this "illusion of truth" memory problem (Skurnik *et al.* 2005).

There is evidence that an extract of "saw palmetto" berries provides relief of problems caused by noncancerous prostate enlargement common among older men. From questioning a convenience sample of older men, Eggers and Fischhoff (2004) found that 40% of 15 men would make choices against their best interests when exposed to a disclaimer. This compares to only 22% of 9 men who would make poor decisions in the absence of the disclaimer.

One variation of each of a test advertisement for a mock anti-hypertensive and for a mock anti-arthritic drug were shown to 676 subjects in groups of 20—of whom about half had high blood pressure or arthritis—during a 17 ½ minute television show. The pairs of advertisements were shown at 1 and 12 minutes into the program. Subjects were much less aware of and knowledgeable about the benefits of the drugs when they were exposed to commercials that included federally mandated disclosures of specific product risks than were subjects who were exposed to the commercials without the mandated disclosures (Morris, Mazis, and Brinberg 1989).

Experimental Evidence Prepared for Court Case on Florida's Implant Dentistry Disclaimer

We conducted an experiment on the effects of the mandatory disclaimer that the State of Florida required dentists to use if they advertised credentials from the American Academy of Implant Dentistry (AAID). We refer to it as the Florida Mandatory Disclaimer or FMD.

All dentists licensed by the Florida State Dental Board are permitted to perform implant dentistry even though few have received formal training in these procedures. The American Academy of Implant Dentistry program offers two credentials—Associate Fellow and Fellow. Each requires substantial skill-training and experience, as is described on the AAID website[10].

Treatment, Subjects, and Administration

Our experiment was designed to measure the extent to which customers comprehend the disclaimers regarding AAID credentials and how these disclaimers affect their decisions. Given the large expenditure and the risk involved in implant dentistry, choosing a dentist to perform implant dentistry is a decision that will typically involve serious deliberation. Thus, consumers and purchasing agents can be expected to attend closely to advertisements and seek further information.

We pre-tested the materials with seven people. Minor modifications to the wording of some questions were made as a result of this pre-testing.

We commissioned Gallup and Robinson to administer the experiment. Neither Gallup and Robinson, nor CRG Global, the fieldwork firm employed by them, was aware of the purpose of the study or the identity of the study's sponsor.

During November 2007, CRG Global interviewed a total of 317 people face-to-face in malls in Orlando, Daytona Beach, and Fort Lauderdale. Potential subjects were screened to ensure that they were over 18 years old and were able to read the English language materials. The interviewers approached 1,053 people in total, 599 declined to participate and 137 did not meet the screening criteria[11]. CRG Global reported that there were no problems with the interviewing.

In order to simulate a high-involvement situation in a realistic way, the interviewers asked subjects to imagine they had a friend in need of implant dentistry. CRG Global conducted the interviews in locations that provided privacy so that subjects would not be distracted or feel rushed.

The subjects were presented with two mock *Yellow Pages* advertisements, each on its own card. Each advertisement was for a single dentist ("Dr. Alan Reed" or "Dr. Barry Smith") and both were headed "IMPLANT DENTISTRY." Both ads described the advertiser as a "General dentist" and carried the statement, "Implant dentistry is a

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[10] http://aaid.com/credentialing/index.html

[11] There is sometimes confusion in court cases about the need for randomization in the experimental design, and the issue was raised in this case. While it is important to ensure that subjects are from the relevant population, the key issue is that the assignment to the experimental treatments be based on a probability design. On the chance that the effect of the disclaimer might have depended on local factors, we conducted the experiments in the area covered by the disclaimer, Florida.

For well over a century, in the social and medical sciences as well as in advertising, convenience samples have been standard practice in experiments. When a tangible item (such as an advertisement) must be shown to a respondent, this has required face-to-face interviews. Jacoby and Handlin (1991) found that marketing researchers used mall interviews on 95% of their face-to-face studies (the others being door-to-door at 3% and other central locations at 2%). None of the studies used probability designs to select the subject pool. Jacoby and Handlin also analyzed papers in academic journals that described "primary empirical research and used samples of people either individually or in groups." Based on a sample of 446 papers from 34 academic journals, they found that 97% of the papers used convenience sampling to select the subject pool.

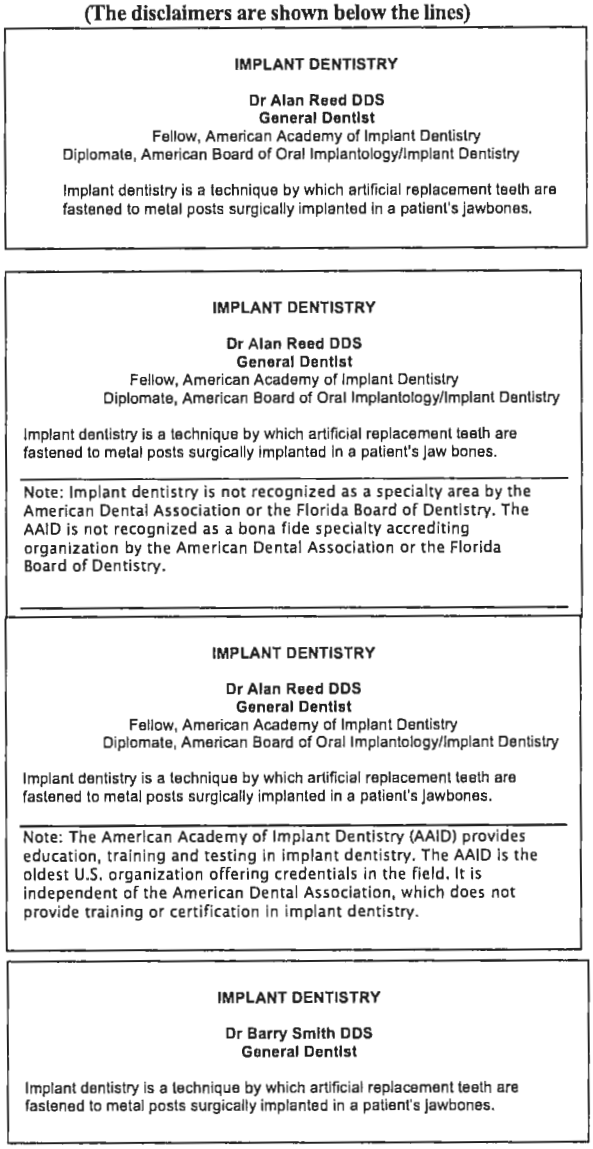
The issue of the random selection of subjects arose also in the previously mentioned Berlex Case, where a New Jersey company was required to provide a disclaimer that they were not affiliated with a West German company with a similar sounding name. The defendants in that case insisted on conducting a replication study using randomly selected subjects. The findings were nearly identical to those from the study that used a convenience sample of subjects.

technique by which artificial replacement teeth are fastened to metal posts surgically implanted in a patient's jaw bones." Other than his name, that is the only information included in Dr Smith's advertisement, and his advertisement was the same for all treatments.

Dr. Reed's advertisement, on the other hand, described him as a Fellow of the AAID and a Diplomate of the ABOI/ID (American Board of Oral Implantology, Implant Dentistry). The information on Dr Reed's credentials was followed by (1) no disclaimer, (2) the Florida mandatory disclaimer, or (3) a modified disclaimer. The "no disclaimer" variation would be illegal under Florida law. Therefore, we wrote the "modified disclaimer" variation with the objective of causing the smallest harm to dentists who advertise AAID credentials while meeting the expressed aims of the Florida legislature in requiring a disclaimer.

One expects an advertisement to present the seller's strongest arguments. In the case of dentists advertising implant dentistry services, this would include the attainment of credentials in implant dentistry. Dr. Smith's advertisement listed no qualification other than a DDS. Dr. Smith was therefore the less qualified of the two dentists. Because Dr. Smith did not have formal implant dentistry qualifications, he was not obliged to include a disclaimer in his advertisement. The four advertisements are shown in Figure 1.

Figure 1: Advertisements used in the experiment
(The disclaimers are shown below the lines)



After the subjects were shown the advertisements, they were asked which dentist (Reed or Smith) they would recommend to their friend.

In roughly half of the interviews, the interviewer collected the advertisements before the subjects were questioned about their understanding of the ads. The numbers of subjects for each treatment are shown in Table 1.

Table 1: Number of subjects by treatment

Ads collected before questions?	Disclaimer used			
	None	FMD	Modified	Total
Yes	55	49	51	155
No	57	51	54	162
Totals	112	100	105	317

Subjects were next asked which of the two dentists they thought had the better implant dentistry qualifications. This was an alternative way of asking which of the two dentists would be the best one to perform implant dentistry on their friend. Finally, subjects were asked demographic questions.

Effects of the Florida Mandatory Disclaimer on Consumers' Decisions

When the advertisement for the AAID-credentialed dentist did not include a disclaimer, 13% of subjects said that they would recommend the other dentist who had no apparent qualifications for implant dentistry. When the advertisement for the AAID-credentialed dentist included the Florida mandatory disclaimer (FMD), 21% said that they would recommend the dentist without implant dentistry credentials. Thus, the FMD led to 1.6 times as many inferior decisions (Table 2).

Table 2: Effects of Florida's Mandated Disclaimer (FMD) on the percentage of subjects who recommended the less-qualified dentist (n = 317)

Subject characteristics	No Disclaimer %	FMD %	Inferior decisions increased by x times
All subjects	13	21	1.6
Education			
No college degree	12	25	2.1
College degree	13	16	1.2
Sex			
Female	13	28	2.2
Male	14	15	1.1

Among those who *did not* see a disclaimer, 12% of subjects without and 13% of those with a college degree would recommend the less-qualified dentist. Among those who *did* see the FMD, 25% of the less-educated subjects would recommend the less-qualified dentist, in contrast to 16% of the better educated said they would do so. In other words, the disclaimer was especially harmful to those with less education.

Prior research shows that for high-involvement products, advertisements should contain only material that is relevant to consumers' decisions (Armstrong 2010). Given that the disclaimer provides information on organizational arrangements among the AAID, American Dental Association, and Florida Board of Dentistry only, it is hard to see why it would be relevant to potential customers or to anyone advising them. This is consistent with the observation of Justices Thomas and Ginsburg in their dissent on an earlier AAID case that "the mandated disclaimer is likely to foster *more* confusion" (*Borgner et al. v. Florida Board of Dentistry et al.* 2002).

Effects of Involvement

We used two additional ways to encourage subjects to process the advertisements carefully, as they would do in a high-involvement situation.

Long-Exposure: Subjects Who Retained The Advertisements

Half of the subjects were allowed to retain copies of the advertisements while they answered our questions. Ironically, those who retained the advertisement that included the FMD were much more likely to be confused about the AAID's role and standing. Substantially larger proportions of those who retained the advertisement agreed with three false statements regarding the AAID's credibility (Table 3). In other words, the longer subjects were exposed to the advertisements containing

the FMD, the greater their level of confusion. Note that the AAID is a *bona fide* credentialing organization that confers credentials only after extensive training and experience. The defendants in the court case did not challenge this.

Table 3: Effect of retaining the advertisement including the Florida Mandatory Disclaimer on perceptions about AAID credibility

	Agreed with incorrect statement	
False Statements	Returned %	Retained %
Not a *bona fide* credentialing organization	39	57
Some accredited members not properly trained	20	43
Special training not necessary for good implant dentistry	18	26

Retesting After Subjects Reflected On Their Understanding

To test whether additional time and examination would reduce confusion, we asked subjects a second time to choose between the dentists after they had answered the questions dealing with their understanding of the advertisements. This time we asked them which dentist they thought was better qualified to do implant dentistry.

Among subjects who were shown the FMD, 19% recommended the less qualified dentist, compared to 12% of those not shown the disclaimer. These responses correspond closely to the earlier results on recommendations of 21% and 13% respectively.

Among subjects who received advertisements with the FMD, 16% of those who returned the advertisements before answering our questions to assess understanding thought the dentist with no apparent qualifications specific to implant dentistry was the better qualified, compared with 22% of those who retained the advertisements. In other words, time for reflection led to more confusion.

Effects of a Modified Disclaimer on Consumers' Decisions and Confusion

We examined the extent that protection for consumers might be provided by a modified disclaimer. We tested one possibility (shown in Figure 2) that we expected would lead to less confusion than the Florida mandated disclaimer. It suffered from the inclusion of a negative word, a problem that we were not able to overcome while adhering to the State's aims for the disclaimer.

Figure 2: Modified AAID Disclaimer

> The American Academy of Implant Dentistry (AAID) provides education, training and testing in implant dentistry. The AAID is the oldest U.S. organization offering credentials in the field. It is independent of the American Dental Association, which does not provide training or certification in implant dentistry.

Of those subjects given an advertisement including the modified disclaimer, 15% recommended the dentist with no qualifications. While this is less than the 21% for those who had received the FMD, it is higher than the 13% for those given no disclaimer. Thus, although the modified disclaimer was less harmful to subjects' decision making than the FMD, it did not eliminate the harm.

Effects of Mandatory Disclaimer on Sellers

Confusion about aspects of the AAID's credibility was higher among subjects who had received the FMD than it was among those who had not. Indeed, 48% of those who were exposed to the FMD agreed or agreed strongly that the AAID was "not a *bona fide* credentialing organization" whereas 36% of those who were not exposed to the FMD believed this.

Because the disclaimer unjustly damages the reputation of the AAID, the FMD also harms individual providers who have AAID credentials—which, in the long run, could cause further harm to consumers by reducing the motivation of dentists to improve their skills in implant dentistry.

Discussion on the Role of Evidence to Support Mandatory Disclaimers

Mandated disclaimers are not free. The costs are passed on to consumers as higher prices and higher taxes. Higher costs lead people, especially the poor, to consider inferior substitutes, such as balancing on chairs rather than buying a ladder. It is

reasonable to ask for evidence of benefits that are greater than these and other costs to support the imposition of a mandatory disclaimer. We have been unable to find a single instance of a mandatory disclaimer for which the criterion of experimental evidence of net benefit was met. We therefore expect that applying that criterion to each proposed restriction of commercial speech would, if applied properly, eliminate mandatory disclaimers.

In practice, however, the "commercial speech" distinction is a tenuous one and the process of putting up evidence and fighting for it in the courts is expensive. When regulators, legislators, interest groups, and business opponents wish to restrict speech, they will be motivated to identify an economic interest on the part of a speaker. That would not be hard to do. Those with an interest in restricting the speech could then call for regulation by constructing an argument that net welfare will increase if the speech is restricted.

Shortly before we submitted our final version of this paper, we learned of a review of the evidence on the related policy of mandated *disclosures* (Ben-Shahar and Schneider 2011). Their review covered not only advertising but also other areas including Miranda rights, informed consent, and Institutional Review Boards. The issue of mandatory disclosures might seem less contentious than mandatory disclaimers as it involves simply providing more information to those who might find it useful. Indeed, mandated disclosures are widespread and enormous sums are spent with the intention of making them useful. In their wide-ranging review of the evidence presented in court cases and in the social science literature, however, the authors found that mandated disclosures seldom provided clear explanations. When consumers do read them—typically they do not—they become confused. In those rare situations when they are not confused, they are unlikely to remember the information, or, if they do, they rarely use it properly. Ben-Shahar and Schneider were unable to find a single mandatory disclosure for which the benefits were shown to outweigh the costs.

When disclosures are shown not to work, regulators try to solve the problem with different (typically longer) disclosures. These efforts to improve disclosures lead to greater harm. Ben-Shahar and Schneider explained that the mandated disclosures fail because they are based on false assumptions about how people make decisions, and they require a chain of unlikely achievements by lawmakers, disclosers, and disclosees[12]. As in our study, the efforts of lawmakers and regulators to improve upon the functioning of markets were shown to be "fatal conceits"[13].

Experimental evidence is consistent with economic theory and prior research on consumer behavior in finding that mandated disclaimers disrupt the functioning of markets. Disclaimers confuse customers, and cause them to be less vigilant when they make decisions. Disclaimers restrict the ability of sellers to provide customers with important information about their products and lead them to follow rules set by officials with inferior knowledge of the market. Moreover, the existence of mandatory disclaimers as a policy option encourages lobbying of politicians and regulators by competitors and by interest groups.

Conclusions

Disclaimers can provide important information to consumers and they have been widely used since the beginning of advertising. Our concern in this paper has been only with the special case of *mandated* disclaimers.

We found that the laws that restrict speech identified as "commercial" with mandates rest on unrealistic economic assumptions about the motivations and behaviors of consumers, business managers, and government officials. Moreover, we found experimental evidence from behavioral research on persuasion that mandatory disclaimers are unlikely to influence consumers in the ways that drafters intend and are likely to influence them in unexpected and detrimental ways.

We then examined evidence from 18 experimental studies related specifically to mandatory disclaimers. In all cases the mandatory disclaimers caused confusion among consumers. Mandated messages increased confusion in all, and were ineffective or harmful in the 15 studies that examined perceptions, attitudes, or decisions.

To date, then, mandatory disclaimers have been imposed at the discretion of officials in contravention of economic understanding, in violation of research on persuasion, and in the face of direct experimental evidence showing that they are detrimental.

Mandatory disclaimers fail to meet the criterion suggested by Justices Thomas and Ginsburg on "the nature and the quality of the evidence a State must present to show that [a disclaimer] directly advances the governmental interest asserted" (*Borgner et al. v. Florida Board of Dentistry et al.* 2002). We suggest an extension to the Thomas and Ginsburg criterion: A mandatory disclaimer should be considered only if experiments demonstrate that it will give rise to net long-term benefits without causing serious harm to any buyers or sellers. Such a test properly applied would likely end the use of mandatory disclaimers.

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[12] They ask readers to imagine that they were a doctor whose duty is to inform a patient of the use of a drug when it has 26 side effects such as heartburn, stomach ulcers, hepatitis, inflammation of skin, itching, life-threatening allergic reactions, and so on. Which side effect would you describe? All? The most likely? The most serious? Would your answer differ if you had seen evidence that this drug kills between 3,000 and 10,000 people per year in the US? Would your answer change if you knew that the drug is aspirin?

[13] F. A. Hayek wrote in *The Fatal Conceit*, "The curious task of economics is to demonstrate to men how little they really know about what they imagine they can design."

We used this extended criterion to re-examine the Florida mandatory disclaimer that was the subject of *Borgner v. Florida Board of Dentistry*. Our experiment showed that the disclaimer confused potential customers, led them to make poor decisions, and unfairly harmed sellers. The judge found our evidence compelling (*Ducoin v. Viamonte Ros* 2009).

By considering the costs and benefits, however, free speech becomes in practice conditional on the opinions of courts and regulators as to whether there is sufficient evidence that a particular speech restriction would increase welfare. They may even decide that the increase of one group's welfare was more valuable than the consequent loss in another's. Free speech then ceases to be a right, as commonly understood and as intended by the First Amendment, but becomes instead an uncertain privilege subject to the opinions of courts and government regulators.

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Appendix
Commercial Speech Restrictions in U.S. Law

The First Amendment to the U.S. Constitution states: "Congress shall make no law…abridging the freedom of speech…". The notion that speech should be subject to a government cost-benefit analysis and judicial opinion strikes us as contrary to the principle of free speech as we understand it and as Benjamin Franklin expounded it.

The States ratified the U.S. Bill of Rights, which includes the First Amendment to the Constitution, on 15 December 1791. Two-hundred-and-twenty years later, in *R.J. Reynolds v. FDA* (2012), the judge upheld what has become a more limited right to speech by granting an injunction against the FDA. Judge Leon granted the injunction, and later granted the plaintiffs' Motion for Summary Judgment, on the basis that the FDA rule requiring tobacco companies to display disturbing color graphic images on the top 50% of the front and back of cigarette packets was, in "substantial likelihood," unconstitutionally compelled speech. He found the images did not constitute "purely factual and uncontroversial information" narrowly tailored for the purpose of informing consumers, but amounted to government advocacy.

The government advocacy in this tobacco case involved tampering with images in order to upset viewers. Presumably it would be illegal for a firm to mislead consumers in this way. Judge Leon noted that the government did not provide relevant scientific evidence. In November 2011, we sent an email request to the FDA asking for its evidence that the new packaging regulations would result in a net social benefit. A copy of our request can be found online[14]. Our requests were met with courteous replies, but scant substantive evidence. We were referred to the Federal Register pages 36628 to 36777 for evidence[15] and were told that no experimental evidence was available. A key statistic, the percentage reduction in smoking was based on a single comparison between Canada, in which a similar graphic warnings policy had been enacted in 2001, and the U.S., in which the policy had not been enacted.

Early Commercial Speech Restrictions

Compelled speech in the form of mandatory warnings was introduced in the U.S. in 1927 with the Federal Caustic Poisons Act (FCPA). Egilman and Bohme (2006) reported that prior to the Act, poisons were sold in bottles of unusual shapes, colors, and textures (they showed an image of a dark-blue skull-shaped bottle) in order to warn consumers, including the blind and illiterate, that the contents were dangerous.

After the passage of the FCPA in the U.S., manufacturers shifted to plain bottles in order to display the mandated warning label. The authors observed that the pre-FCPA bottles were more effective at protecting at least some people. The FCPA created the agency which three years later became known, as it is currently, as the Food and Drug Administration.

Exceptions that limited freedom of speech identified as commercial began to be made following *Valentine v. Chrestensen* (1942). The U.S. Supreme Court justices ruled that a New York City ordinance that was used to prohibit the owner of a submarine from distributing advertising material (handbills) on the streets was not a violation of the First Amendment right to free speech—even when the material included a statement of political protest and no prices. Prior to this opinion, the court did not make a commercial speech distinction (Boedecker, Morgan and Wright 1995).

Having created a commercial speech exception to free speech rights, the Supreme Court did not specifically uphold the right to disseminate "truthful and nonmisleading commercial messages about lawful products and services" until 1975. Subsequent judgments provided further clarification of this limited right (Boedecker, Morgan and Wright 1995; *44 Liquormart Inc. v. Rhode Island* 1996, 496). In contrast, citizens, consumer groups, and lobby groups—which often speak against commercial interests in order to further their own—have First Amendment protection to speak about products; protection that is denied to firms, even to the extent that Nike was denied the right to speak in its own defense against media coverage of lobbyists (Shugan 2006).

The Central Hudson Test of Commercial Speech Restriction, and Subsequent Developments

Recall that in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council* (1976), the Supreme Court Justices stated, "we see no satisfactory distinction between the two kinds of speech…As to the particular consumer's interest in the free flow of commercial information, that interest may be as keen, if not keener by far, than his interest in the day's most urgent political debate."

Despite the Justices' own concerns about the practical difficulties of holding to the concept of a commercial speech distinction, the Supreme Court did not abandon the concept. Instead, from 1980 the Court provided guidelines for making the distinction in ways that further reduced freedom by allowing considerable discretion to governments and courts to judge the importance of regulating the speech in question (Boedecker, Morgan and Wright 1995).

In *Central Hudson v. Public Service Commission of New York* (1980) the Supreme Court set out the requirements that must be met in order to warrant government regulation of commercial speech. Namely, there must be a substantial government interest that might be served by a restriction on speech, the regulation of the speech must directly advance that interest, and the restriction of speech must be no greater than is necessary to serve that interest. While concurring with the

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[14] http://kestencgreen.com/letter-to-fda.pdf

[15] Available online at http://www.gpo.gov/fdsys/pkg/FR-2011-06-22/pdf/2011-15337.pdf

judgment, Justices Brennan, Blackmun, and Stevens variously argued that the Court's definition of commercial speech encompassed speech "entitled to the maximum protection afforded by the First Amendment" (Stevens) and that the speech test was too permissive of government regulation.

In relation to mandatory disclaimers and warnings, the U.S. Supreme Court stated, "We do not suggest that disclosure requirements do not implicate the advertiser's First Amendment rights at all. We recognize that unjustified or unduly burdensome disclosure requirements might offend the First Amendment by chilling protected commercial speech. But we hold that an advertiser's rights are adequately protected as long as disclosure requirements are reasonably related to the State's interest in preventing deception of consumers" (*Zauderer v. Supreme Court of Ohio* 1985). Justices Brennan and Marshall elaborated that the State must "demonstrate that the advertising either 'is inherently likely to deceive' or must muster record evidence showing that 'a particular form or method of advertising has in fact been deceptive'... and it must similarly demonstrate that the regulations directly and proportionately remedy the deception." The Justices also noted that compelling the publication of information that is large in quantity relative to the advertiser's information "would chill the publication of protected commercial speech and would be entirely out of proportion to the State's legitimate interest in preventing potential deception."

In *SUNY v. Fox* (1989), the Supreme Court weakened the *Central Hudson* condition that regulation of speech should be "not too extensive", requiring instead only that regulation should be "reasonable" and noted that it would not hold government regulation of commercial speech to the "least restrictive means," as the dissenting Justices argued was required under *Central Hudson*.

The Florida Department of Business and Professional Regulation reprimanded a lawyer for "false, misleading, and deceptive" advertising for advertising her Certified Public Accountant (CPA) and Certified Financial Planner (CFP) credentials (*Ibanez v. Florida* 1994). In this case, which parallels the *Ducoin v. Viamonte Ros* (2009) case for which we conducted our research, the CFP credential was conferred by a private organization and the Department required Ibanez to display a form of the Florida Mandatory Disclaimer. The Supreme Court held that the Board's censure of Ibanez was "incompatible with First Amendment restraints on official action." In particular, the Court rejected the requirement for a disclaimer on the grounds that hypothesized possible deception was not sufficient grounds for rebutting "the constitutional presumption favoring disclosure over concealment." Further, Justice Ginsburg observed that "the detail required in the disclaimer currently described by the Board effectively rules out notation of the 'specialist' designation on a business card or letterhead, or in a yellow pages listing."

Over the years since the review by Boedecker, Morgan and Wright (1995), more than a dozen U.S. Supreme Court decisions have cited the key *Central Hudson* judgment, and seven of these were germane to this paper.

In *Rubin v. Coors* (1995), Coors Brewing sought to include alcohol content on bottle labels. The government sought to restrict Coors speech in order to keep consumers ignorant of the alcohol content of beer, evidently for the sake of their own protection. The Justices found the Federal Alcohol and Tobacco Administration Act clause that prohibits that practice violated the First Amendment right to free speech, because it failed the *Central Hudson* test. Justice Stevens concurred that the labeling ban was unconstitutional but, in a dissenting opinion, claimed that the *Central Hudson* test was not relevant when the legislation was a plain attempt to suppress truthful information that was of interest to consumers.[16]

The Supreme Court found that a Florida Bar rule that prohibited injury lawyers from sending direct mail solicitation to victims or their relatives before 30 days after the accident or disaster passed the *Central Hudson* test for the restriction of commercial speech and did not therefore violate the First Amendment (*Florida Bar v. Went For It* 1995). The Florida Bar rule was based on surveys of public opinion, complaints, newspaper editorials, concerns that victims should not be exposed to invasion of privacy and undue influence, and concerns that the reputation of the legal profession was harmed by the practice of soliciting recent victims. In the opinion of the Court, delivered by Justice O'Connor, the nature of evidence that is needed to satisfy the *Central Hudson* test is at the discretion of the Court, and may be none. The Court was concerned not so much with whether harm was inflicted on the recipients of the advertising material, who could easily make the short trip from mailbox to trashcan, but with the potential damage to the reputation of the legal profession.

Justice Kennedy's dissent, with Justices Steven, Souter, and Ginsburg joining, was scathing of the majority opinion upholding the prohibition. He wrote, "This scheme makes little sense. As is often true when the law makes little sense, it is not first principles but their interpretation and application that have gone awry." He concluded:

> "Today's opinion is a serious departure... from the principles that govern the transmission of commercial speech. The Court's opinion reflects a new-found and illegitimate confidence that it... knows what is best... Self-assurance has always been the hallmark of a censor. That is why under the First Amendment the public, not the State, has the right and the power to decide what ideas and information are deserving of their adherence."

In *44 Liquormart Inc. v. Rhode Island* (1996), the Court followed *Rubin v. Coors* and found that the government of Rhode Island had violated the First Amendment protection of free speech by banning the advertising of alcoholic beverage prices. All Justices concurred but differed in their reasoning. Delivering the Court's opinion, Justice Stevens drew a distinction between State regulation of commercial messages for the purpose of protecting or informing consumers and the

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[16] The same legislation required *disclosure* of alcohol content on wine and spirit labels.

complete prohibition on disseminating truthful and non-misleading commercial messages for other reasons. He argued that the latter situation provided "far less reason to depart from the rigorous review that the First Amendment generally demands" (p. 501). Justice Stevens warned that commercial speech bans typically rested solely on the paternalistic premise that people will respond "irrationally" to the truth and need to be kept in the dark for their own good. He further warned that banning speech would conceal the government policy from the public and hence from debate. Justice Stevens rejected the State's claim that commercial speech about "vice" products were not entitled to First Amendment protection, pointing out that such an exception would allow state legislatures to impose censorship on lawful activities by characterizing them as vices.

Justice Thomas argued that the government has no legitimate interest in keeping purchasers ignorant in order to manipulate their choices, and therefore the *Central Hudson* test did not apply. Moreover, Justice Thomas professed skepticism over making a commercial speech distinction: "I do not see a philosophical or historical basis for asserting that 'commercial' speech is of 'lower value' than 'noncommercial' speech" (p. 522). He pointed out that application of the *Central Hudson* test, as interpreted by Justices Stevens and O'Connor in this case, would stop the government from restricting commercial advertising except where it outlaws or otherwise restricts the transactions themselves, because these measures would more effectively achieve the government purpose.

Justice Scalia shared Justice Thomas's "discomfort with the *Central Hudson* test" as seeming to "have nothing more than policy intuition to support it" (p. 517). Justice Thomas observed that the *Central Hudson* test is difficult to apply uniformly, given that it is subject to individual judicial preferences and judges' opinions as to which situations citizens cannot be trusted with information on and for which products consumption should be discouraged. He suggested a return to the holding of *Virginia Board of Pharmacy* (1976).

In *Greater New Orleans Broadcasting v. U.S.* (1999), Justice Stevens presenting the opinion of the Court acknowledged the difficulty of applying the Central Hudson test and that there were calls for its replacement by "a more straightforward and stringent test for assessing the validity of governmental restrictions on commercial speech." The Court, however, decided that it was not appropriate to tackle the broader constitutional issue when the test provided "an adequate basis for decision" for the case before it.

In presenting the Court's opinion on *Lorillard Tobacco Co. v. Reilly* (2001), Justice O'Connor suggested that the Court's established position on the Central Hudson test's requirement for empirical data to support regulation of commercial speech is not an onerous one, but can be met with "studies and anecdotes" from different situations, or even "history, consensus, and 'simple common sense.'" In respect to the cost-benefit test, the Court maintained that, "A careful calculation of the costs of a speech regulation does not mean that a State must demonstrate that there is no incursion on legitimate speech interests, but a speech regulation cannot unduly impinge on the speaker's ability to propose a commercial transaction and the adult listener's opportunity to obtain information about products."

In his partial concurrence, Justice Thomas reasserted his opposition to drawing a commercial speech distinction, as he also did in *Greater New Orleans Broadcasting v. U.S.* He restated his position that there is no historical or philosophical basis for assigning commercial speech a lower value than other speech and adding that it is doubtful "whether it is even possible to draw a coherent distinction". On the question of whether tobacco is a product that is so exceptional as to be outside any First Amendment consideration, Justice Thomas concluded his opinion with the following uncompromising statement about the intended scope of the First Amendment:

> No legislature has ever sought to restrict speech about an activity it regarded as harmless and inoffensive. Calls for limits on expression always are made when the specter of some threatened harm is looming. The identity of the harm may vary. People will be inspired by totalitarian dogmas and subvert the Republic. They will be inflamed by racial demagoguery and embrace hatred and bigotry. Or they will be enticed by cigarette advertisements and choose to smoke, risking disease. It is therefore no answer for the State to say that the makers of cigarettes are doing harm: perhaps they are. But in that respect they are no different from the purveyors of other harmful products, or the advocates of harmful ideas. When the State seeks to silence them, they are all entitled to the protection of the First Amendment.

Pharmacists who wished to advertise that they could supply drugs in compounded and other convenient forms for customer had their right to do so affirmed by the Supreme Court in *Thompson v. Western States Medical Center* (2002). Justice O'Conner, delivering the majority opinion of the Court noted, "We have previously rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information." In a dissenting opinion, Justices Breyer, Stevens, and Ginsburg maintained that the Court's opinion had given insufficient regard to the government's role as protector of consumers from untested products, citing evidence that physicians believe that advertising leads consumers to pressure them to prescribe drugs they would not otherwise prescribe. The dissenting justices argued that commercial speech should be subject to government policy objectives and to less rigorous First Amendment protection.

In *Milavetz, Gallop and Milavetz. v. United States* (2010), the Court upheld a requirement for lawyers who offer bankruptcy advise or assistance to include in their advertisements notice that their operation is a "Debt Relief Agency" that "helps people file for bankruptcy". The plaintiffs claimed that these statements would cause confusion among consumers, but did not offer evidence. The majority opinion, delivered by Justice Sotomayor, held that the likelihood that consumers would be misled if the mandated statements were absent was self-evident.

Should We Put a Price on Free Speech?

J. Scott Armstrong
Kesten C. Green

Should public policy guarantee First Amendment rights to all citizens, at all times? Some of our commentators think not. We argue there is good reason to hold to rights.

Consistent with economic theory and behavioral research, experimental findings show that mandatory disclaimers harm producers and consumers. They are also expensive to develop and to enforce.

Perry and Blumenthal (in this issue) show that similar problems exist with respect to the broader area of mandatory *disclosures*. Their findings conflict with the common assumption that "more information is better," and demonstrate that confusion occurs even when negative words can be avoided. The problem is that people are overwhelmed with information that has little relevance to their decision-making. We do not agree with their statement that experimental evidence is "necessary to examine the effects of disclosures on decision quality and to improve public policy and consumer protection." The burden of proof should be on those who would deny the right of free speech. Furthermore, sufficient experimental evidence exists, and it favors retaining free speech.

Taylor and Capella (in this issue), provide a wide-ranging and useful literature review. Then they take a similar position as Perry and Blumnethal, stating, "a wholesale moratorium on mandatory information provision appears unwarranted." They base this statement on the argument that "sound disclosure is grounded in the public's right to know and corporate ethics." They do not, however, provide any experimental evidence to support their argument or their implicit assumption that government lawmakers and enforcers will behave more ethically than people working in firms.

We encountered a similar status quo bias among some of the people who provided unpublished comments on our paper. We are not sure why we have to prove to them that it is wrong to deprive business people of First Amendment rights. And we are not sure how it would be possible to do so: they were unable to tell us what evidence would convince them. Normally it is up to the government to prove the case beyond a reasonable doubt when trying to take away a person's freedom, say by putting them in jail.

As is shown by Sherman (in this issue), courts have been lax in supporting free speech. They have assumed that government restrictions on free speech are of obvious benefit and thus need no support from evidence. There are exceptions, of course, as in Judge Leon's blocking of the FDA's attempt to force tobacco sellers to use visuals (some of which were falsified) and text to persuade people to stop smoking. In that case, the government, armed with an enormous budget, failed to provide experimental evidence to support the imposition of speech restrictions[i].

In the spirit of evidence-based policy, it would be reasonable to ask that each restriction on speech must be shown beyond a reasonable doubt to confer benefits that are greater than all the costs. Because things change, it would also be reasonable to ask that the case be made again, say every five years, with the same requirement for rigorous evidence.

While it is *reasonable* to ask for comprehensive cost-benefit analyses for government policies, we wonder whether it is *proper* to conduct cost-benefit analyses for the right to free speech. Should we consent to our governments going through each right in the Bill of Rights and decide whether the potential dangers of freedom outweigh the benefits? To do so would be to ignore the years of struggle and lives spent to obtain and retain basic freedoms. Our ancestors put great value on these freedoms. It seems naïve to think they were wrong to do so.

Since we were unable to find experimental evidence to support even one successful use of a mandatory disclaimer over the roughly 70 years and thousands of applications of this policy in the U.S., we conclude that conducting cost-benefit analyses would support the right to free speech. However, conducting comprehensive and open analyses is enormously expensive, while holding to established rights of free speech is, as they say, "free."

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[i] *R.J. Reynolds Tobacco Co et al. v. U.S. Food and Drug Administration et al.* (2012), U.S. District Court for the District of Columbia, No. 11-cv-1482. [Available from www.ana.net/getfile/16887]

Board Certification

Board Certification is the process by which dentists (DDS, DMD), physicians (MD, DO) or other health care practitioners in the United States demonstrate through written, oral, practical, and/or simulator based testing, a mastery of the basic knowledge and skills that define an area of dental/medical specialization. The commonly used acronym BE/BC (board eligible/board certified) refers to a doctor who is certified, or is eligible to be certified, to announce specialization in a particular area of practice. Prior to taking the examination, a dentist or physician must graduate with a degree, either DDS, DMD, MD or DO, complete approved post-graduate training and meet all other prerequisites to certification as set forth by the certifying agency or "board." Board Certification helps ensure the public that formal training has been completed and a sufficient knowledge base in the specialty has been demonstrated.

Procedure for Recognition of New Certifying Boards

Gabapentin to buy online (https://web.archive.org/web/20180627203509/http://dustinhallphotography.ca/) 1. Criteria

A dental certifying board that seeks membership in the American Board of Dental Specialties **http://planetapaz.org/es/noticias-olaneta-paz/126-noticias-2014/1103-sentencia-t-135-13 (https://web.archive.org/web/20180627203509/http://planetapaz.org/es/noticias-olaneta-paz/126-noticias-2014/1103-sentencia-t-135-13) must:**

- Reflect a distinct and well-defined area of expertise in dental practice, above and beyond that provided at the level of pre-doctoral dental education, that is founded in evidence-based science, contributes to professional growth and education, and concerns the practice of dentistry.
- Develop a rigorous standard of preparation and evaluation in the dental specialty area.
- Provide evidence of psychometric evaluation of the written and oral examination processes for a period of time sufficient to ensure validity and reliability.
- Provide an effective mechanism to maintain certification.
- Exist as an independent, self-governing entity whose main purpose is to evaluate candidates for board certification in a field of dentistry.

go to site (https://web.archive.org/web/20180627203509/http://thelakotaculturalexchangeprogram.org/wp-login.php) 2. Application Process

- The application and related documentation should be directed to:

American Board of Dental Specialties
Executive Director
211 East Chicago Avenue, Suite 750C
Chicago, IL 60611
312-818-2070
888-371-3595 Fax
office@dentalspecialties.org
(https://web.archive.org/web/20180627203509/mailto:office@dentalspecialties.org)

The completed application must include a non-refundable application fee.

3. Specialty

ABDS recognizes that there are varying levels of education and training required for board certification within specific areas of dentistry. The Levels and their specific requirements for education, training and experience are:

- **diclofenaco 50mg bula agener (https://web.archive.org/web/20180627203509/http://kiplrn.com/diclofenaco-50mg-bula-agener.html) Dental Specialty**

Certifying boards seeking Dental Specialty must require a minimum of two (2) full-time, formal, advanced educational programs that are a minimum of two (2) years in duration and are presented by recognized educational institutions: Any alternate pathway must demonstrate it is equivalent with didactic, clinical and completed cases to their two-year post-graduate training program.

4. Approval as a Dental Specialty Board

- Following approval by the ABDS, the newly approved dental specialty board may announce through its members, its website or in press releases, that it has been certified as a dental specialty board by the American Board of Dental Specialties.

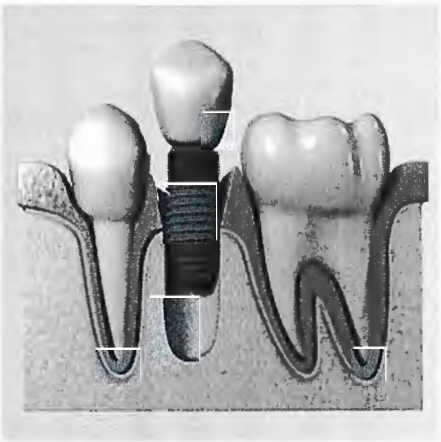
- The approved board will become a member of ABDS with all rights and privileges as outlined in the ABDS Bylaws.

5. Denial as a Dental Specialty Board

- If the application is deemed incomplete, ABDS will send a letter outlining any perceived deficiencies after which the applicant board has thirty (30) days to respond and to address the deficiencies. Within ninety (90) days after receipt of the applicant board's response/additional information. ABDS will issue its decision.

- Should the decision of ABDS be to deny the application, the applicant board may file a written appeal to the ABDS Executive Director within three (3) months after receipt of the denial. The applicant board may request reconsiderations and may be granted an informal hearing with ABDS.

Board Certification



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(https://web.archive.org/web/20161103215554/mailto:sbennett@dentalspecialties.org)

The completed application must include a non-refundable application fee.

3. Specialty and Subspecialty

ABDS recognizes that there are varying levels of education and training required for board certification within specific areas of dentistry. Therefore, ABDS has established two (2) Dental Specialty Levels. The Levels and their specific requirements for education, training and experience are:

Level 1 – Dental Specialty

Certifying boards seeking Dental Specialty must require a minimum of two (2) full-time, formal, advanced educational programs that are a minimum of two (2) years in duration and are presented by recognized educational institutions: or require 400 didactic hours and the equivalent of one (1) year of clinical practice.

Level II – Subspecialty of General Dentistry

Certifying board seeking Subspecialty of General Dentistry must require a minimum of six (6) months formal education presented by a recognized educational institution: or a minimum of 100 didactic hours plus the equivalent of a minimum of one (1) year of clinical practice.

4. Approval as a Dental Specialty Board

- Following approval by the ABDS, the newly approved dental specialty board may announce through its members, its website or in press releases, that it has been certified as a dental specialty board by the American Board of Dental Specialties.

- The approved board will become a member of ABDS with all rights and privileges as outlined in the ABDS Bylaws.

5. Denial as a Dental Specialty Board

- If the application is deemed incomplete, ABDS will send a letter outlining any perceived deficiencies after which the applicant board has thirty (30) days to respond and to address the deficiencies. Within ninety (90) days after receipt of the applicant board's response/additional information. ABDS will issue its decision.

- Should the decision of ABDS be to deny the application, the applicant board may file a written appeal to the ABDS Executive Director within three (3) months after receipt of the denial. The applicant board may request reconsiderations and may be granted an informal hearing with ABDS.

Board Certification

Board Certification is the process by which dentists (DDS, DMD), physicians (MD, DO) or other health care practitioners in the United States demonstrate through written, oral, practical, and/or simulator based testing, a mastery of the basic knowledge and skills that define an area of dental/medical specialization. The commonly used acronym BE/BC (board eligible/board certified) refers to a doctor who is certified, or is eligible to be certified, to announce specialization in a particular area of practice. Prior to taking the examination, a dentist or physician must graduate with a degree, either DDS, DMD, MD or DO, complete approved post-graduate training and meet all other prerequisites to certification as set forth by the certifying agency or "board." Board Certification helps ensure the public that formal training has been completed and a sufficient knowledge base in the specialty has been demonstrated.

Procedure for Recognition of New Certifying Boards

1. Criteria

A dental certifying board that seeks membership in the American Board of Dental Specialties **must:**

- Reflect a distinct and well-defined area of expertise in dental practice, above and beyond that provided at the level of pre-doctoral dental education, that is founded in evidence-based science, contributes to professional growth and education, and concerns the practice of dentistry.
- Develop a rigorous standard of preparation and evaluation in the dental specialty area.
- Provide evidence of psychometric evaluation of the written and oral examination processes for a period of time sufficient to ensure validity and reliability.
- Provide an effective mechanism to maintain certification.
- Exist as an independent, self-governing entity whose main purpose is to evaluate candidates for board certification in a field of dentistry.

2. Application Process

- The application and related documentation should be directed to:

American Board of Dental Specialties
Executive Director
211 East Chicago Avenue, Suite 750C
Chicago, IL 60611
312-818-2070
888-371-3595 Fax

office@dentalspecialties.org
(https://web.archive.org/web/20170303151309/mailto:office@dentalspecialties.org)

The completed application must include a non-refundable application fee.

3. Specialty and Subspecialty

ABDS recognizes that there are varying levels of education and training required for board certification within specific areas of dentistry. Therefore, ABDS has established two (2) Dental Specialty Levels. The Levels and their specific requirements for education, training and experience are:

Level 1 – Dental Specialty

Certifying boards seeking Dental Specialty must require a minimum of two (2) full-time, formal, advanced educational programs that are a minimum of two (2) years in duration and are presented by recognized educational institutions: or require 400 didactic hours and the equivalent of one (1) year of clinical practice.

Level II – Subspecialty of General Dentistry

Certifying board seeking Subspecialty of General Dentistry must require a minimum of six (6) months formal education presented by a recognized educational institution: or a minimum of 100 didactic hours plus the equivalent of a minimum of one (1) year of clinical practice.

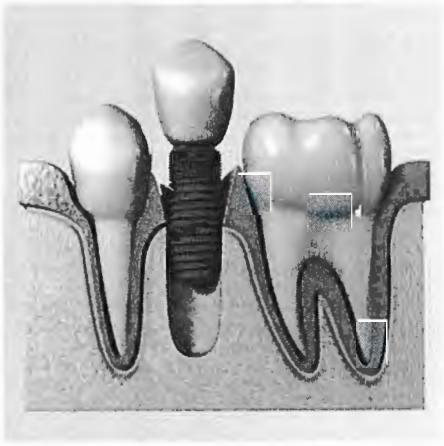
4. Approval as a Dental Specialty Board

- Following approval by the ABDS, the newly approved dental specialty board may announce through its members, its website or in press releases, that it has been certified as a dental specialty board by the American Board of Dental Specialties.
- The approved board will become a member of ABDS with all rights and privileges as outlined in the ABDS Bylaws.

5. Denial as a Dental Specialty Board

- If the application is deemed incomplete, ABDS will send a letter outlining any perceived deficiencies after which the applicant board has thirty (30) days to respond and to address the deficiencies. Within ninety (90) days after receipt of the applicant board's response/additional information. ABDS will issue its decision.
- Should the decision of ABDS be to deny the application, the applicant board may file a written appeal to the ABDS Executive Director within three (3) months after receipt of the denial. The applicant board may request reconsiderations and may be granted an informal hearing with ABDS.

Board Certification



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Requirements for Recognition of Dental Certifying Boards

A dental certifying board that seeks membership in the American Board of Dental Specialties must fulfill the following requirements as determined by the ABDS:

- A. Exists as an independent entity whose primary purpose is to evaluate candidates for board certification.
- B. Provides a certification process that reflects a distinct and well-defined expertise in dental practice, is founded in evidence-based science, contributes to professional growth and education, and directly benefits clinical patient health.
- C. Requires a minimum of a 2-year, full-time, formal, advanced educational program or equivalent with well-defined, evidenced-based educational standards.
- D. Demonstrates that candidates for certification have acquired advanced knowledge and skills that are above and beyond that provided at the level of pre-doctoral dental education in the defined area of dentistry
- E. Provides a mechanism to maintain certification
- F. Provides evidence that it has conducted psychometrically based testing of candidates for a minimum of 5 years.
- G. Meets or exceeds standards of existing ABDS boards in similar fields.

Procedure for Recognition of New Certifying Boards

- A. The application and related documentation should be directed to the Executive

Director of ABDS. Applications will be accepted no sooner than early 2015.

- B. The ABDS may solicit comments from communities of interest in regard to the applicant.
- C. The ABDS may conduct an open hearing before making a recommendation on any application.
- D. The application should adhere to the following outline:
    - 1. The name of the proposed certifying board asking for approval.
    - 2. The objectives and function of the proposed certifying board.
    - 3. The name, composition and governance systems of any related organizations.
    - 4. A detailed statement describing how compliance with each of the Requirements is achieved.
    - 5. A description of the applicant organization, the names and professional qualifications of the applicant board of directors.
    - 6. A copy of the current Constitution and Bylaws including all amendments and any mission statements that are not part of the Bylaws.
    - 7. A copy of the Articles of Incorporation.
    - 8. An outline of the qualifications to be required of applicants for certification.
    - 9. The names of educational pathways meeting the ABDS requirements.
    - 10. The number of dentists certified by the applicant board since inception, listing active and inactive status.
    - 11. A copy of the proposed application form for candidates for certification.
    - 12. A checklist of documents for the applicant including the following;
        - a. A list of current directors and officers of the Board, indicating when their terms expire including a list or chart of staff positions and duties and a list of Board committees and advisory committees.
        - b. The Board's website and any printed literature for the proposed specialty.
        - c. Any director and officer liability insurance policy and a summary of other insurance coverage for the organization.
        - d. List any current or past litigation regarding the credentialing process.
        - e. The ABDS shall submit a progress report to applicant Board within one year after receipt of the complete application.
        - f. The petitioner may file a formal appeal in the event of a negative decision by the ABDS. The petitioner must file a written appeal to the Executive Director of the ABDS within.
- E. The ABDS shall submit a progress report to applicant Board within one year after receipt of the complete application.
- F. The petitioner may file a formal appeal in the event of a negative decision by the ABDS. The petitioner must file a written appeal to the Executive Director of the ABDS within 60 days

of notification of a negative decision detailing the reasons for the appeal.

- G. Procedures for approval of new certifying boards and related application material will be reviewed, and if needed, modified on a biannual basis.

Applications may be obtained by contacting the ABDS Executive Office no sooner than early 2015.

Specialty Exams

CDCA administers examinations for several states in six specialty areas:

- Endodontics
- Orthodontics
- Oral & Maxillofacial Surgery
- Pediatric Dentistry
- Periodontics
- Prosthodontics

Specialty Examinations are not designed to replace the specialty boards, but to qualify successful applicants to practice and to advertise themselves as specialists in the states participating in this specialty examination process. (Currently, this includes: Idaho, New Mexico, Oklahoma, Oregon, Texas, and Utah.)

These states may require the Specialty Examination administered by the CDCA for specialty licensure. Check with the appropriate state dental board.

Generally, other states do not require this examination for specialty licensure. However, on a case-by-case basis, some states may request special consideration.

Specialty Exam Information Form

Exam Specifics

The examination window for 2021 has passed. Dates for 2022 will be posted by mid-January.

The examination consists of two parts:

1. A written multiple-choice examination of 160 to 180 questions
2. Presentation of a series of cases completed by the candidate demonstrating specific treatment planning and technical skills.

Candidates may take one or both parts of the examination as described below.

Documented cases, models, and case histories must be sent to Specialty Examination, The Commission on Dental Competency Assessments, 1304 Concourse Drive, Suite 100, Linthicum, MD 21090, and received no later than (TBD for 2022).

A score of 75% or better is required in both parts to pass. If you receive a passing score on the written portion of the American Board in your specialty, the written part of the CDCA exam can be waived.

Note: *State rules and regulations are constantly changing. To assure the most current licensure requirements, always check with the state dental board in the state where you intend to practice.*

Additional information:

Payment deadline: (TBD for 2022)

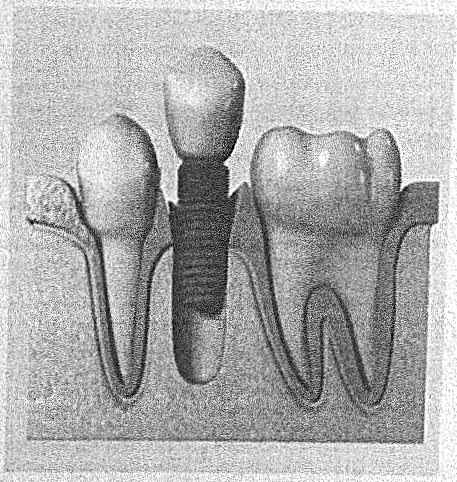
Candidates will be notified of their assigned examination time on or about (TBD for 2022).

Refunds will not be issued for verbal sections after (TBD for 2022).

Refunds will not be issued for written sections after (TBD for 2022).

Exam Registration FAQs

Board Certification



Board Certification is the process by which dentists (DDS, DMD), physicians (MD, DO) or other healthcare practitioners in the United States demonstrate through written, oral, practical, and/or simulator based testing, a mastery of the basic knowledge and skills that define an area of dental/medical specialization. The commonly used acronym BE/BC (board eligible/board certified) refers to a doctor who is certified, or is eligible to be certified, to announce specialization in a particular area of practice. Prior to taking the examination, a dentist or physician must graduate with a degree, either DDS, DMD, MD or DO, complete approved post-graduate training and meet all other prerequisites to certification as set forth by the certifying agency or "board." Board Certification helps ensure the public that formal training has been completed and a sufficient knowledge base in the specialty has been demonstrated.

Procedure for Recognition of New Certifying Boards

1. Criteria

A certifying board that is seeking membership in the American Board of Dental Specialties must:

1. Exist as an independent, self-governing entity whose purpose is to evaluate candidates for board certification;
2. Certify diplomates in a distinct and well-defined area of expertise in dental practice, above and beyond that provided at the level of pre-doctoral dental education; that is founded in evidence-based science; contributes to professional growth and education; and encompasses the practice of dentistry;
3. Utilize a rigorous standard of education preparation and evaluation in the dental specialty area, including at least 2 full-time established advanced education programs;
4. Provide evidence that the diplomate examination is psychometrically evaluated in a manner sufficient to validate the examination;
5. Provide documentation of an effective mechanism to maintain or recertify diplomate status over time, including evidence of adequate board- approved continuing education.

3. Specialty

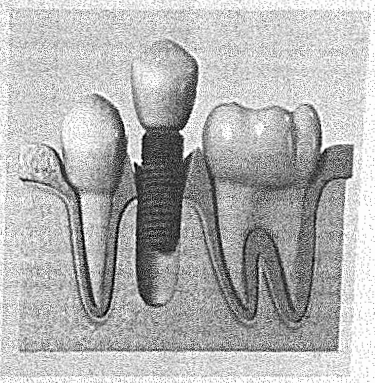
ABDS recognizes that there are varying levels of education and training required for board certification within specific areas of dentistry. The Levels and their specific requirements for education, training and experience are:

Dental Specialty

Certifying boards seeking Dental Specialty must require a minimum of two (2) full-time, formal, advanced educational programs that are a minimum of two (2) years in duration and are presented by recognized educational institutions: Any alternate pathway must demonstrate it is equivalent with didactic, clinical and completed cases to their two-year post-graduate training program.

EXHIBIT 19

Board Certification



Board Certification is the process by which dentists (DDS, DMD), physicians (MD, DO) or other health care practitioners in the United States demonstrate through written, oral, practical, and/or simulator based testing, a mastery of the basic knowledge and skills that define an area of dental/medical specialization. The commonly used acronym BE/BC (board eligible/board certified) refers to a doctor who is certified, or is eligible to be certified, to announce specialization in a particular area of practice. Prior to taking the examination, a dentist or physician must graduate with a degree, either DDS, DMD, MD or DO, complete approved post-graduate training and meet all other prerequisites to certification as set forth by the certifying agency or "board." Board Certification helps ensure the public that formal training has been completed and a sufficient knowledge base in the specialty has been demonstrated.

Requirements for Recognition of Dental Certifying Boards

A dental certifying board that seeks membership in the American Board of Dental Specialties must fulfill the following requirements as determined by the ABDS:

- A. Exists as an independent entity whose primary purpose is to evaluate candidates for board certification.
- B. Provides a certification process that reflects a distinct and well-defined expertise in dental practice, is founded in evidence-based science, contributes to professional growth and education, and directly benefits clinical patient health.
- C. Requires a minimum of a 2-year, full-time, formal, advanced educational program or equivalent with well-defined, evidenced-based educational standards.
- D. Demonstrates that candidates for certification have acquired advanced knowledge and skills that are above and beyond that provided at the level of pre-doctoral dental education in the defined area of dentistry
- E. Provides a mechanism to maintain certification
- F. Provides evidence that it has conducted psychometrically based testing of candidates for a minimum of 5 years.
- G. Meets or exceeds standards of existing ABDS boards in similar fields.

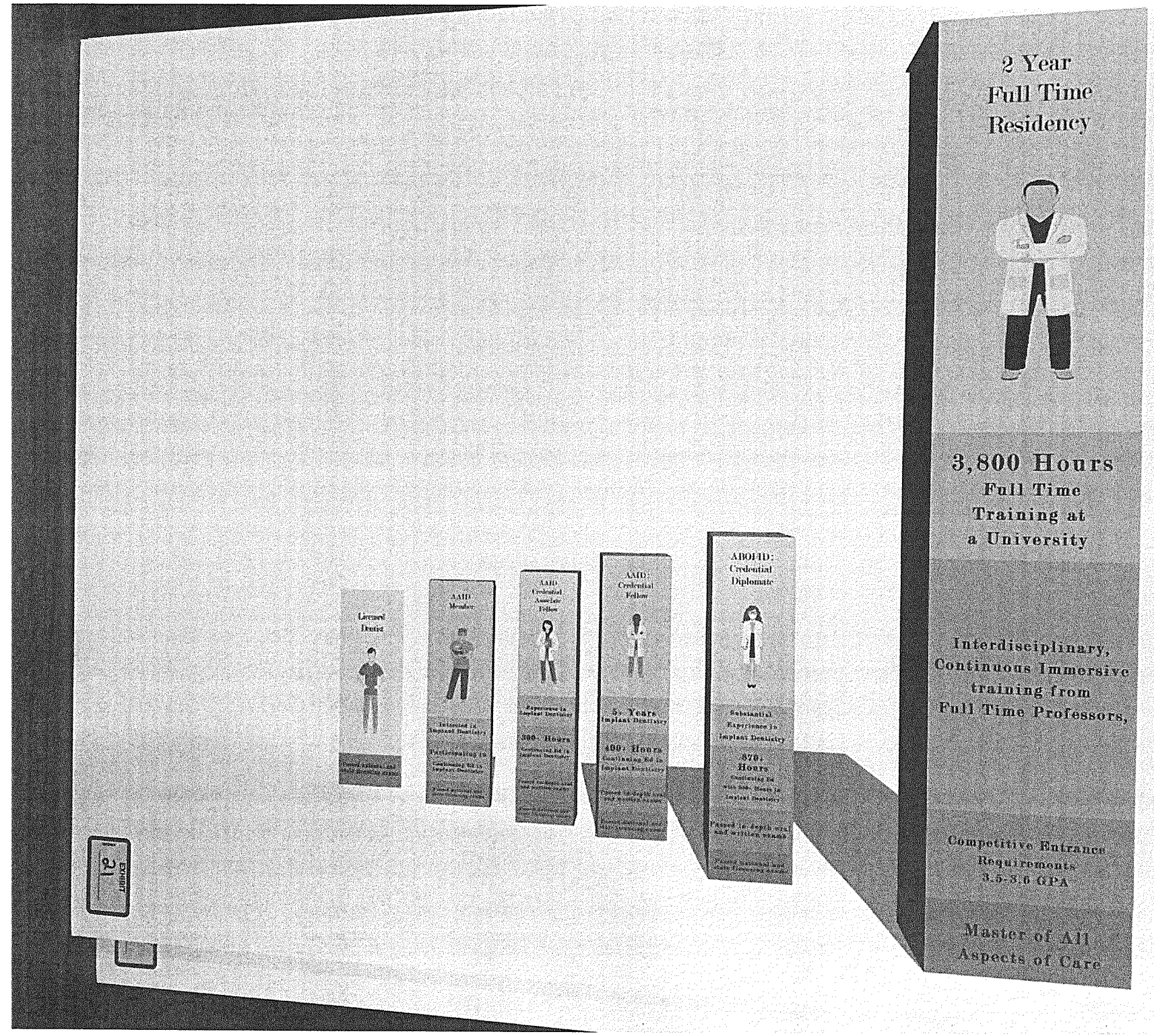
EXHIBIT 18

ABDS

- Required evidence-based processes for the evaluation and recognition of dental certifying boards
  - Incorporated and independent organization
  - Minimum of two (2) two-year or more dedicated post graduate programs in the specific specialty based at a US university or hospital
  - Council on Dental Accreditation (CODA) approved
  - Written and oral examination of the candidates specific to the specialty which are regularly psychometrically evaluated and supported
  - Regular process of recertification of those candidates that are certified

EXHIBIT 19


Licensed Dentist
6100 Est. Hours of Dental School
2 Year Full Time Residency
3,800 Hours Full Time Training at a University
EXHIBIT
120


Licensed Dentist
AAID Member
Interested in Implant Dentistry
Participating in Continuing Ed in Implant Dentistry
AAID Credential Associate Fellow
Experience in Implant Dentistry
300+ Hours
AAID: Credential Fellow
5+ Years Implant Dentistry
400+ Hours
ABOHID: Credential Diplomate
Substantial Experience in Implant Dentistry
870+ Hours
2 Year Full Time Residency
3,800 Hours Full Time Training at a University
Interdisciplinary, Continuous Immersive training from Full Time Professors,
Competitive Entrance Requirements 3.5-3.6 GPA
Master of All Aspects of Care

LOMA LINDA UNIVERSITY

Course Title		Prosthodontics	Implant Dentistry
Interdisciplinary			
GRDN 514	Introduction to Biomedical Research	4.0	4.0
GRDN 535	Clinical Oral Pathology	2.0	2.0
GRDN 605	Professional Ethics	2.0	2.0
GRDN 621A	Biomedical Science	2.0	2.0
GRDN 621B	Biomedical Science	2.0	2.0
REL 5__	Graduate-level Religion	3.0	3.0
GRDA 533	Radiology Topics for Graduate Dental Programs	2.0	2.0
GRDN 607	Practice Management	2.0	
OMFS 606	Selected Topics in Oral and Maxillofacial Surgery (1)		4.0
OMFS 626	Applied Surgical Anatomy		1.0
Totals		**19.0**	**22.0**
Overall Totals		**125.0**	**134.0**

Course Title		Prosthodontics	Implant Dentistry
Clinical			
PROS 715	Clinical Practice of Prosthodontics (4)	44.0	
IMPD 725	Clinical Practice in Implant Dentistry (4)		44.0
IMPD 726	Clinical Practice in Periodontics in Implant Dentistry (2)		6.0
IMPD 727	Clinical Practice of Prosthodontics in Implant Dentistry (2)		20.0
Totals		**44.0**	**44.0**

Fulfills general boarding requirement

Normal time to complete the program

Four and one-half (4.5 years) full-time enrollment required

LOMA LINDA UNIVERSITY

Dual Major — Prosthodontics, Implant Dentistry Comparison

Closed to admissions for the 2022-2023 academic year

Major	Course Title	Prosthodontics	Implant Dentistry
[redacted]	Dental Bioengineering	2.0	2.0
[redacted]	Introduction to Implant Dentistry	2.0	2.0
[redacted]	Advanced Implant Dentistry	2.0	2.0
[redacted]	Occlusion and Morphology	2.0	2.0
[redacted]	Occlusion: Principles and Instrumentation	2.0	2.0
[redacted]	Removable Partial Prosthodontics	3.0	3.0
[redacted]	Complete Denture Prosthodontics	3.0	3.0
[redacted]	Advanced Complete Denture Prosthodontics	3.0	3.0
[redacted]	Fixed Partial Prosthodontics	3.0	3.0
[redacted]	Advanced Fixed Partial Prosthodontics I (Mil. Aesthetics)	3.0	3.0
[redacted]	Maxillofacial Prosthetics	3.0	3.0
[redacted]	Prosthodontic Literature Review (2)	11.0	6.0
[redacted]	Removable Partial Prosthodontics Literature Review	3.0	
[redacted]	Complete Denture Prosthodontics Literature Review	3.0	
[redacted]	Patient Presentation Seminar (Prosthodontics, Implant, Perio) (12)	9.0	
[redacted]	Practice Teaching in Prosthodontics	3.0	
[redacted]	Dental Materials Science	2.0	
[redacted]	Clinical Application of Dental Materials	1.0	
[redacted]	TMJ Function and Dysfunction	1.0	
[redacted]	Advanced Removable Partial Prosthodontics	3.0	
[redacted]	Literature Review in Implant Dentistry for Prosthodontists (2)	3.0	
[redacted]	Diagnosis and Treatment Planning (3)	18.0	
[redacted]	Geriatric Dentistry	1.0	
[redacted]	Scholarly Activity in Prosthodontics	1.0	
[redacted]	Patient Presentation Seminar (12)		12.0
[redacted]	Implant Dentistry Grant Review (12)		12.0
[redacted]	Implant Prosthodontics (3)		18.0
[redacted]	Literature Review in Implant Dentistry (3)		23.0
[redacted]	Current Literature Review in Implant Dentistry (3)		18.0
[redacted]	Oral Implant Surgery (2)		11.0
[redacted]	Diagnosis and Treatment Planning in Implant Dentistry (12)		12.0
[redacted]	Peri-Implant Histopathology		1.0
[redacted]	Practice Teaching in Implant Dentistry		3.0
[redacted]	Scholarly Activity in Implant Dentistry		1.0
[redacted]	Periodontal Therapy (2)		6.0
[redacted]	Moderate Sedation in Periodontics		4.0
Totals		[redacted]	[redacted]

23

AAID Boston MaxiCourse
Harvard Club of Boston
2021-2022

The Scope of Implant Dentistry
Brian J. Jackson, DDS
Diplomate- ABOI/ID
Fellow- AAID
Director/ MaxiCourse Boston

Maxillary Sinus Augmentation: Lateral/Crestal Approach

Brian J. Jackson, DDS
Diplomate- ABOI/ID
Fellow- AAID
Director/ MaxiCourse Boston

Treatment Planning and Tx- Posterior Maxilla

- Posterior Maxilla- treatment considerations
- Treatment planning and prosthetic considerations
- Prosthetic protocols and materials

Hands on: Sinus surgery- Lateral approach (model, egg)

- **Videos**
- **Lunch and learn- Tx planning session**

Objectives: At the end of the module, the participants will:

- Comprehend advanced surgical procedures via CBCT analysis
- Learn fundamental extraction protocols for immediate implant placement
- Learn various bone grafting materials and utilization in maxillary sinus augmentation
- Perform "hands on" sinus surgery (lateral/crestal) on model
- Be able to determine when to utilize lateral vs crestal approach for sinus augmentation
- Comprehend implant occlusal principles and biomechanics for the fixed prosthesis
- Understand key considerations in regards to patient medical history
- Review case presentations to reinforce implant concepts

EXHIBIT 24

LIVE CLINICAL TRAINING

AAID MaxiCourse, Utah

Module 1 starts October 20, 2023

AAID MaxiCourse

The most advanced course in implant dentistry and the only complete clinical live patients training program in US!

Program includes placement of up tp 4 implants & restorative on live patients.

This in-depth program will discuss all phases of implant placement while examining the diagnostic and treatment modalities necessary to offer exceptional care for your patients. The 300 hour interdisciplinary approach utilizes casebased learning methodology that will include: lectures, demonstrations, interactive seminars, hands-on sessions, LIVE clinical patient treatment, and relevant reviews of literature emphasizing evidence-based clinical approaches. Path to AAID Fellowship.

The program provides for didactic & participation requirements for qualifying exams of AAID credentialing. Certificate of

ADA CERP

Roseman University is an ADA CERP Recognized Provider. ADA CERP is a service of the American Dental Association to assist dental professionals in identifying quality providers of continuing dental education. ADA CERP does not approve or endorse individual courses or instructors, nor does it imply acceptance of credit hours by boards of dentistry.

Roseman University designates this for 300 CE credits.

EXHIBIT 85

Full Arch Conversion

Four-Day Course

Introduction

Mentoring IV (M4) is an All-on-X program with live full-arch guided surgery for all attending doctors. All 12 participants will perform full-arch surgery on a partially to fully edentulous patient.

Each patient will leave the institute with either a PMMA or a denture that has been converted chairside during the course. This is advanced implant surgery that focuses on surgical and prosthetic considerations that allow clinicians to design and execute a predictable and immediate smile for their patients.

Prerequisite for M4: Must have placed a minimum of 20 implants and have restored a full arch with either a fixed or removable prosthesis.

Live Surgery

During the surgical days, participants will be performing a full-arch surgery as well as delivering an immediate provisional restoration. During the ongoing surgeries, our lab technicians will be assisting in the operatories to facilitate immediate, chairside conversions.

This course is only held at our home office location in Charlotte, NC.

Summary

This course will provide you with an understanding of how to successfully execute a full-arch surgery and deliver an immediate provisional the same day. Day One includes lectures by [redacted] our laboratory partner, and our partner in guided surgery. Also included in Day One is a hands-on workshop with surgical models.

Days Two to Four are surgical days. There will be two arches scheduled each day with doctors rotating through the surgeries at different stages. Doctors are encouraged to assist and/or observe for all stages of all surgeries to which they are assigned.

Introduction to Implant Placement

Three-Day Course

Introduction

This course allows participants to spend two pre-surgery days learning strategies about safe and predictable implant placement. The lecture portion of the program covers everything, from anatomy and patient selection to complications and tissue management.

The lecture is followed by a hands-on workshop to review proper drilling protocols and implant placement. On the final day of the program, participants will perform implant placement on a live patient.

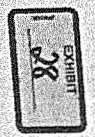
Live Surgery

All attending doctors will perform live implant placement on a selected patient provided by the [redacted]. Supervision and guidance are provided by [redacted] and his mentors to all participants performing surgery.

The day of surgery is interactive and collaboration is encouraged. After each dentist completes his/her own surgery, he/she is welcome to observe and/or assist in the several other surgeries taking place.

SPECIALIST REQUIREMENTS (limited to Periodontists, Prosthodontists & Oral Maxillofacial Surgeons)

LEVEL	Online Examination	Oral Examination	Cases Presented	Case Examples
Master *Surgical Track *Restorative Track *Combination - Surgical/Restorative Track	1 hour	1 hour	3	3 cases - surgical or restorative, all representative of the chosen track. For the Combination Track, 3 cases - any combination of surgical and restorative.
Diplomate *Surgical Track *Restorative Track *Combination - Surgical/Restorative Track	1 hour	2 hours	5	*Surgical specialty:* 2 without grafting, 3 grafted with 2 multiple implants per arch; *Prosthetic specialty:* 2 single unit, 3 multiple either fixed or removable implant supported prostheses; *GP or dual specialist:* 1 without grafting, 1 grafted with multiple implants, 1 single unit restoration, 1 multiple implant restoration, and 1 implant supported overdenture or fixed RPD.



Educational Parameter	CODA Accreditation	CE Hour Compilation
Trainee Selection	Competitive selection based on academic and other accomplishments	Nonselective; admission open to any fee-paying dentist
Curricular design	Comprehensive outline of experiences in progression, must meet detailed and specific content specifications	Unstructured and uncoordinated collection of educational experiences, high probability of repetitive and/or missing content
Assessment of trainee learning	Validated formative and summative assessments are mandatory	Participant knowledge and ability are rarely assessed formally
Program direction	A single qualified Program Director must assume responsibility for all aspects of the training program	The trainee is responsible for his or her own curriculum design and implementation
Competency assurance	Program Director must attest to competency of graduate	CDE certificates document "participation" or "attendance," not competence, no final, cumulative competency assessment is made
Learning environment	Longitudinal immersive exposure with progressively graduated experiences	Episodic courses/learning events without overall coordination
Supervision of technical experiences	Faculty oversight with ongoing feedback and progressive independence	Most clinical experience is derived outside the educational environment, self-supervised and self-assessed
Scope of training	Generally trained beyond ultimate level of practice	Most courses offer exposure to basic competence in a focused skill set
Accreditation	Training program itself is accredited	Institution is certified as a CDE provider
Accreditation process	Rigorous, ongoing process evaluating faculty, curriculum, and educational outcomes	Course policies assessed for unbiased content delivery; content itself and educational outcomes receive little attention

EXHIBIT 29

Dr. Hilt Tatum a past president of AAID and later a past president of ABOI said in a 2021 AAID news article, "By 1983 progress on the goal for university residency programs was progressing well with a full department at Harvard, four active residency programs, and five more being developed; however, the commercialization of the field in 1984 stopped this entire effort with only one program surviving. This has led to a 37- year period of dental school educators not developing residency training in comprehensive oral implantology."

Dr. Duke Heller past resident of AAID in AAID news 2021 issue 4 opines that they want implantology training to flourish as a full time residencies, "IMPLANT DENTISTRY WILL BECOME A SPECIALITY in the future. I believe this with all my heart. In the next five to ten years, many dentistis will be able to comeplete a comprehensive implant program from dental school faclty."

- Founding date: 1961, eight campuses all over the globe
- Student body: More than 5,000 per year
- Number of graduates: Around 300,000 since its founding
- Hamburger University is a real degree-granting institution
- Hamburger U is a member of an accredited association of degree-granting schools in the US
- overall acceptance rate at Harvard University, admitting only 3.4% of all applicants. The acceptance rate at the Shanghai campus of Hamburger University is a mere 1%.
- As a matter of fact, in 2005, it was awarded 46 college credit recommendations by ACE.
- Unlike a traditional bachelor's degree, a Hamburgerology degree consists of only 23 credits, although students holding senior managerial positions within the McDonald's system can earn up to 27 credits.
- around 1,600 colleges and universities in the US honor HU credits,
- You can't just apply to Hamburger University through the Common App or Coalition App — you have to be invited to attend it.

EXHIBIT 31