The Use of Botox in the Practice of Dentistry Requires Caution

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Botox is a drug made from the same bacterium that causes food poisoning. Used properly, Botox injections can actually help alleviate some health problems. The Food and Drug Administration (FDA) first approved Botox in 1989 and, since its initial approval, its FDA approved uses have expanded to encompass various medical conditions including urinary incontinence, chronic migraines, cervical dystonia, and certain types of eye muscle problems.1 In 2002, the FDA approved Botox Cosmetic (botulinum toxin type A) for purely cosmetic use to improve the look of moderate to severe frown lines between the eyebrows (glabellar lines), and in 2013 it was approved for temporary improvement of “crow’s feet” in adults. Botox has been proven to be a very effective, nonsurgical tool in cosmetic treatment. Since the effects of Botox last only about four to six months, claims of serious permanent injuries are infrequent.2 In 2012 alone, over 4 million cosmetic procedures were performed.

2. On February 8, 2008, the FDA did publish a notice that Botox Cosmetic (botulinum toxin type A) and Myobloc (botulinum toxin type B) had been linked in some cases to adverse reactions, including respiratory failure and death, following treatment of a variety of conditions using a wide range of doses. The adverse reactions appeared to be related to the spread of the toxin to areas distant from the site of injection, mimicking symptoms of botulism. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2008/ucm116857.htm.

continued on page 5
Case Study

Treatment Delays Lead to Necrotizing Fasciitis

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A 49-year-old patient was seen by a dentist employed by a union-owned and operated dental clinic. The patient was a very heavy smoker and had poor dental hygiene. Fourteen of his teeth had cavities and he had a large amount of plaque and tartar. He also was edentulous in 3 quadrants.

The patient’s first visit was in January, 2008. The dentist made and discussed an extensive treatment plan with the patient that would take many months to complete. The dentists at the clinic had no control in scheduling patients for appointments or referrals. This was performed by the clinic’s clerical staff. The length of appointments was limited and it was not always possible to complete a procedure during a visit. The timing of follow-up appointments or referrals also was not within the control of the employed dentists.

The patient was given an appointment with the hygienist for mid-February. He kept the appointment, but, when seen in mid-March, he clearly was noncompliant with recommendations for the maintenance of his oral hygiene. The patient failed to keep his next appointment in April, 2008, and did not return for treatment until September of 2008, when teeth #1 and #2 were excavated and filled. On December 1, 2008, tooth #9 was excavated and filled. He did not keep his next appointment on December 8, 2008, but appeared one week later on December 15, 2008, for a root canal on tooth #7. However, the root canal was not fully completed at that appointment. The dentist did prescribe antibiotics after that visit. On April 13, 2009, the dentist completed the root canal on tooth #7 and again prescribed antibiotics. One week later, cavities on teeth #20 and #21 were excavated and filled.

In early May of 2009, another cavity on tooth #21 was excavated and filled. At that appointment, the dentist recommended a root canal for tooth #29. The patient’s next two appointments were in mid-July, 2009. Cavities in teeth #21, #22 and #27 were excavated and filled, a post was placed in tooth #7, and the core built up.

Six months later, on January 25, 2010, the dentist performed a therapeutic pulpotomy on tooth #29, prescribing both antibiotics and pain medication after the procedure was completed. The next and last visit with this dentist was on March 22, 2010. The dental record contained documentation that the crown on tooth #29 had broken to the gingiva. Because the patient also had broken tooth #28 below the gumline several years before coming to the clinic in 2008, extraction of the root fragments of both teeth, #28 and #29, was recommended. Neither tooth had caused him any pain, but the canal of tooth #29 was exposed.

The dentist referred the patient to an oral surgeon for that procedure. He was given a list of potential oral surgeons to call for an appointment. The dentist did not prescribe antibiotics at this visit. The clinic staff, however, did take a Panorex film before the patient left the premises as per union policy. This allowed the patient to take this film to the oral surgeon so that the union would not be charged for another Panorex by the oral surgeon. The dentist, however, never reviewed the Panorex before or after the patient left the clinic.

Apparently, several days after the visit, the temporary filling on tooth #29 fell out. The patient never called to notify the dentist of this. For a period of 11 days after the last visit, the patient had no pain or problems with either tooth #28 or #29. However, on April 2, 2010, he began to experience pain in tooth #29 and some facial swelling, for which he took Aleve. The pain continued to increase on April 3 and on April 4, it was severe enough that he called in sick to his employer. He described the pain as 10 out of 10. He continued to take Aleve, but did not go to either his physician or the emergency department (ED). At 2:00 a.m. on April 5, the pain was so unbearable that he finally went to the ED.

On admission, his temperature was 102.5°. He was promptly admitted to the Intensive Care Unit (ICU). He was initially diagnosed with cellulitis, bilateral swollen submandibular glands, subcutaneous emphysema, and supraglottic edema. The history he provided was that he had had a bad toothache for a week. He was then taken emergently to surgery. A tra-
cheotomy was performed, along with the dental extraction of teeth #28 and #29. A mediastinal drain was placed and several muscles were resected and debrided. Cultures were performed and grew streptococcus milleri. He was treated with vancomycin and piperacillin. Despite this, his white blood count substantially increased.

The patient was returned to surgery. The area was re-explored, debrided, washed, and packed. The patient was returned to the ICU critically ill. There, he further developed pleural effusions, possible pneumonia, obstruction at the left brachiocephalic vein, and a pericardial effusion. A gastrostomy (feeding) tube (G-tube) was placed. The surgeons made a definitive diagnosis of necrotizing fasciitis and mediastinitis. His platelets began to decrease and he was transfused. He also developed symptoms of alcohol withdrawal in the ICU, which were consistent with a history of excessive alcohol use/abuse.

On April 11, 2010, the patient was again returned to the operating room for debridement of the mediastinum and a thoracotomy. Over the next few weeks, despite his initially critical condition, the patient stabilized and began to improve. On April 29th, he was diagnosed with dysphagia. A swallowing study confirmed that he was aspirating both thin and thick liquids. Finally, by May 2, 2010, he had improved sufficiently to be discharged. A home care agency was retained to provide wound care to his neck and to teach him and his wife how to perform G-tube feedings. On May 27, 2010, the patient underwent reconstruction of the neck flap. On June 23, he had a repeat swallowing study which confirmed continued aspiration. On September 6, 2010, another swallowing study confirmed aspiration of only thin liquids.

The patient still has a G-tube in place. He is limited to eating only soft solid food. He also has extensive neck scars and suffers from, and continues to be treated for, depression. The patient commenced a lawsuit against the dentist and the dental clinic. The dentist was insured by MLMIC; the clinic, by another carrier. The case was reviewed on behalf of MLMIC by both a dental expert and an infectious disease expert. It was then submitted to the District Dental Claims Committee (DDCC).

The MLMIC dental expert had several serious concerns about the dentist's care. The first was the performance of a root canal over the course of two visits, four months apart. Further, although the dentist clearly had no ability to change the frequency of appointments or referrals, the patient should have been advised to see an oral surgeon promptly. That discussion definitely should have been documented, yet there was nothing in the patient’s record. This became especially problematic because the patient disputed that any such discussion had occurred, and instead opted to wait to see an oral surgeon since the referral did not expire until May 2, 2010.

Although the dental expert criticized the failure of the dentist to read the Panorex as “sloppy” care, he did not necessarily consider that to be a deviation from the standard of care.

dentist promptly commenced. The clinic, which controlled the time between care because of the condition of the involved teeth at that visit.

The MLMIC infectious disease expert concurred with the MLMIC dental expert that the defense was compromised because there was no documentation that the dentist advised the patient that he must see an oral surgeon immediately. Further, although the defined treatment for these teeth was extraction, he too was critical of the dentist’s failure to prescribe antibiotics, under the circumstances. Strep milleri is a common pathogen in dental cases. If an antibiotic had been prescribed, that, together with prompt extraction, would likely have helped to prevent this infection.

Both experts also pointed to culpable conduct on the part of the plaintiff. He waited to go to the oral surgeon; he was not compliant with recommended oral hygiene; when the filling on tooth #29 fell out, he did not contact the dentist; and, he delayed calling the dentist, his physician and/or going to the ED for several days despite being in severe pain and having a swollen face. However, this apparently did not impact the amount of the damages eventually paid.

Finally, the DDCC recommended prompt settlement by the dentist. It found there was a delay in treatment due to the failure to advise the patient that seeing an oral surgeon was urgent, since there was no documentation to counter the plaintiff’s story. It acknowledged that there were problems in the way the clinic operated, but felt it was the dentist’s responsibility to be sure that each patient is clear about what he or she needs to do next. They also were critical that the dentist neither read the Panorex nor prescribed antibiotics at the patient’s last visit.

Settlement discussions on behalf of the dentist promptly commenced. The patient’s final visit was considered to be a deviation from the standard of care because of the condition of the involved teeth at that visit.
appointments and the scheduling of referrals, was initially quite resistant to participating in any settlement but finally agreed to do so. The case was eventually settled before trial by both defendants for the sum of $1.5 million. $1 million (2/3) was paid on behalf of the dentist and $500,000 (1/3) was paid on behalf of the clinic.

**A Legal & Risk Management Perspective**

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A dentist who is employed by a large organization may face unique challenges in patient care. As in this case, the dentist may not have control over his/her own schedule, patient appointments, or patient referrals. The employer’s organization may be system-driven and not readily adaptable to changes or exceptions. Such an environment can present a heightened risk of professional liability.

Even in situations where the dentist is an employee and bound by the employer’s administrative policies, the dentist still has an independent professional obligation to his/her patients, and still must practice within the standard of care. Sometimes, the employer’s policies may present barriers to the recommended treatment plan for a patient. In such a case, the dentist is left with a dilemma as to how to handle the conflict. Recognizing that the dentist may be placed in a difficult position, in 2013, the American Dental Association published guidance in the form of a Statement Regarding Employment of a Dentist to address several concerns in the employer-employee relationship. It states that employers and employees should recognize and honor the guidelines in the policy statement to promote safe, high-quality, and cost-effective patient care. Specifically, it states in relevant part:

[D]entists’ paramount responsibility is to their patients. An employee dentist should not be disciplined or retaliated against for exercising independent professional judgment in patient assessment, diagnosis, treatment and comprehensive management.

Because a dentist is functioning within a professional domain, anyone employing a dentist should, for example:

1. Guard against lay interference in the exercise of a dentist’s independent professional judgment in patient assessment, diagnosis, treatment and comprehensive management.

   In the present case, all the defense experts, as well as the District Dental Claims Committee, found that there was a delay in treatment which caused the serious injuries suffered by the plaintiff. The experts were critical of the dentist’s failure to promptly and appropriately treat the patient and arrange for continued care. The dentist should not have allowed the clinic’s scheduling system to interfere with professional standards of care. The patient’s root canal treatment should have been fully completed in one visit rather than on two visits four months apart. Further, the dentist should have personally arranged a timely appointment with an oral surgeon to address the urgency of the plaintiff’s condition, or else otherwise assured himself that the plaintiff had a timely appointment arranged by the clinic’s staff. In situations such as this, where the patient needs urgent attention by a specialist, it would have been a best practice to arrange the appointment either prior to the patient’s departure from the office or within a very short time afterward, and document it in the chart. Had the dentist done so, the lawsuit may have been avoided.

   Finally, the lack of critical documentation in this case was a pivotal issue resulting in the payment to the plaintiff. Although the dentist claimed that he advised the patient to promptly see an oral surgeon, nothing was ever documented in the chart. The patient disputed that he was ever told that it was important to obtain an appointment right away. The referral form used by the clinic did not indicate it was an urgent matter and, therefore, the patient did nothing until he experienced an emergency. Again, if the patient had been treated earlier, it is likely his damages would have been lessened or even nonexistent. Without any documentation in the chart, the dentist had no hard evidence to counter the plaintiff’s version of events or to prove he appropriately counselled the patient. The dentist should not only have informed the patient of the urgency of the need to see an oral surgeon, and assisted in obtaining a prompt appointment, but should also have documented the entire encounter thoroughly and completely. In the absence of such documentation, the dentist’s care could not be adequately defended.

involving Botox, and that number is likely to increase.³

Procedures involving Botox are performed by physicians in any number of medical specialties. Dentists who have special expertise in oral and maxillofacial areas may well claim to be particularly suited to administer Botox to the facial, peri-oral and oral areas, where dental practice is focused. It is therefore not surprising that more and more dentists are using Botox in the course of dental treatment. Botox is frequently used in conjunction with dermal filler therapy (collagen).

As the frequency of Botox use increases in dentistry, practitioners must be aware of the limitations imposed by the New York State Education Law.

§ 6601. Definition of Practice of Dentistry.
The practice of the profession of dentistry is defined as diagnosing, treating, operating, or prescribing for any disease, pain, injury, deformity, or physical condition of the oral and maxillofacial area related to restoring and maintaining dental health. The practice of dentistry includes the prescribing and fabrication of dental prostheses and appliances. The practice of dentistry may include performing physical evaluations in conjunction with the provision of dental treatment.

In 2008, The New York State Board for Dentistry explained how the state’s licensing statute affects the ability of dentists to use Botox and collagen in the practice of dentistry. In a written opinion, then Acting Executive Secretary Lawrence H. Mokhiber stated:

This section does not specify modalities of practice and does not limit the practice of dentistry to any specific methods of treatment. As a result, Education Law does not prohibit a New York State licensed dentist from using botulinum toxin type A and collagen in the oral and maxillofacial area, consistent with Section 6601, as long as it is related to restoring and maintaining dental health. When providing such services, the dentist must also be competent to provide such services. Rules of the Board of Regents Section 29/1(b) (9) defines unprofessional conduct as: “practicing or offering to practice beyond the scope permitted by law, or accepting and performing professional responsibilities which the licensee knows or has reason to know that he or she is not competent to perform, or performing without adequate supervision professional services which the licensee is authorized to perform only under the supervision of a licensed professional, except in an emergency situation where a person’s life or health is in danger.” Therefore, it is incumbent upon a dentist to provide all services within the defined scope and competently. Whether a specific use of these modalities is lawful would depend upon the circumstances presented.

In short, the use of Botox and dermal fillers is allowed provided it is used as a part of “restoring and maintaining dental health.” If a NYS licensed dentist administers Botox and/or collagen to the oral and maxillofacial area strictly for cosmetic purposes, unrelated to restoring and maintaining dental health, it would subject the dentist to penalties for professional misconduct. For example, in 2011, a dentist was subject to a 3-month license suspension, a 21-month stayed suspension, 2 years probation, and a $7,500 fine for the use of Botox in his dental practice unrelated to any dental condition.⁴


continued on page 8
Legal Defense Only Coverage

MLMIC’s Dentists and Oral Surgeons Professional Liability Policy contains additional provisions to protect our policyholders in the event they are faced with a governmental investigation. This coverage, referred to as “defense only” or “legal defense only,” provides to individual dentists, at no additional premium, payment of up to $25,000 for the costs of defending against certain proceedings. The coverage will apply for: (1) an administrative action brought against a dentist by a governmental body, such as the Office of Professional Discipline (OPD), arising out of allegations which could form the basis of a claim of legal liability under the policy, and (2) a governmental proceeding alleging Medicare/Medicaid fraud or abuse related to violation of Medicare or Medicaid guidelines arising out of filing an erroneous claim seeking payment for reimbursement. (See Section I, 5. Supplementary Payments, (3) a. Defense-With a Limit (a) & (b) of the policy for terms and conditions).

If you are contacted by the OPD regarding a complaint, or are facing a governmental proceeding alleging Medicare/Medicaid fraud, you should contact the MLMIC claims department at your earliest opportunity in order to avail yourself of the above coverage provision. It is in your best interest to refrain from discussing the matter with anyone without representation by legal counsel.

The coverage for administrative actions or governmental proceedings differs from a claim or law suit brought against you alleging professional malpractice, and is, therefore, handled differently by the Company. Unlike a covered malpractice claim or law suit, coverage for “defense only” is limited to payment for the costs of your defense up to the limit of $25,000. For example, unlike a malpractice case, you select the attorney who will represent you. MLMIC can provide you with contact information for law firms that have experience representing dentists in “defense only” cases to aid in your selection. Also, unlike a malpractice case, a “defense only” action is managed between yourself and your choice of legal counsel. Again, MLMIC is there to pay only the associated defense costs as provided by the terms and conditions of your policy.

To contact the appropriate MLMIC claims department: if you practice in the upstate area (all counties above Rockland and Westchester), please call our Syracuse Office at 888-744-6729; our downstate policyholders (Rockland, Westchester, and below) should contact our Long Island Office at 888-263-2729.

Dentist and Oral Surgeon Underwriting Update Application

Changes in your practice could impact coverage. Therefore, MLMIC periodically requires you to complete a “Dentist and Oral Surgeon Underwriting Update Application.”

In early 2014, MLMIC commenced a new on-line process for our dentist policyholders to update their practice information on the MLMIC.com website. Every year one third of our dentist policyholder base will receive a mailed notice advising that they are required to complete an update, along with instructions on how to access the on-line update application. This process enables an on-going review of important underwriting information on a 3-year cycle.

So, when you receive a request to complete your Underwriting Update, we ask that you please give it your prompt attention, in order that MLMIC has the most current and accurate information for you on file.

Of course, in the interim, should you have any changes in your practice, please contact an underwriter: in NYC at 800-683-7769; in Long Island at 888-263-2729; and Upstate at 888-744-6729.
**RISK MANAGEMENT Tip**

**Tip: Promoting Communication Between the Referring and the Consulting Dentists**

**The Risk:**
Lack of communication between dentists can result in a delay in diagnosis or treatment, the failure to act upon abnormal test results or findings, the duplication of a prescription, or failure to prescribe appropriate medications or order diagnostic testing. A lack of clearly defined roles and responsibilities for all dentists may impede your ability to provide and promote safe and effective patient care.

**Recommendations:**
1. Referring dentists should develop a method for determining whether a consultation has been completed and if a written report has been received.
2. As a matter of standard office policy, all consultation reports must be reviewed by a dentist, initialed, and dated prior to being filed in the patient’s dental record.
3. Office follow-up procedures should provide for easy identification of a patient’s noncompliance with the recommendation for a referral, such as when a written report has not been received from the consultant.
4. If a patient has been non-compliant in obtaining the recommended referral/consultation, written follow-up with the patient is necessary. Your discussion with the patient should include reinforcement of the necessity and reason for the referral/consultation, as well as documentation in the patient’s dental record of all attempts to contact the patient and obtain compliance.
5. If a written report from the consultant is not received in a timely manner, you should contact the consultant to determine whether a written report has been generated.
6. Consulting dentists should routinely send written reports to referring dentists in a timely manner. These reports should include: findings; recommendations, including interventions, and the delineation of the dentist responsible for treatment; and follow-up of abnormal test results, including incidental findings.
7. To promote effective communication, the consultant should contact the referring dentist about any patient who fails to keep an appointment. Dental record documentation should reflect the missed appointment, as well as notification of the referring dentist.
8. Telephone conversations between referring and consulting dentists are important when clarification of the contents of a report is necessary. Timely contact must be made when an urgent or emergent clinical finding is identified. These conversations must also be documented in the patient’s dental record.

**Fager Amsler & Keller’s attorneys are available during normal business hours to assist MLMIC insureds with a wide range of legal services, including, but not limited to, advisory opinions concerning liability issues, liability litigation activities, lecture programs, and consulting services.**

Healthcare law, regulations, and practices are continually evolving. The information presented in Dental Dateline is accurate when published. Before relying upon the content of a Dental Dateline article, you should always verify that it reflects the most up-to-date information available.
The Use of Botox continued from page 5

**Botox and Collagen for Restoring and Maintaining Dental Health**

There are therapeutic uses for Botox that are within the scope of practice of dentistry, including: adjunctive therapy in TMJ and bruxism cases; as an alternative to surgically treating high lip line cases; treatment of denture patients who have trouble adjusting to new dentures; retraining of facial muscles in orthodontic treatment; an alternative therapy in cases of sialorrhea (drooling) to inhibit the production of saliva; relief of hemifacial spasms; treatment of facial asymmetries; treatment of salivary fistulas; treatment of oromandibular dystonia; and treatment of blepharospasm. Dermal fillers can also be used therapeutically in high lip line cases as an alternative to: gingivectomy; crown lengthening and veneers; treatment of angular chelitis; eliminating “clack triangles” between teeth after periodontal and implant treatment that did not preserve the papilla; re-establishing lip volume for proper phonetics (in addition or as opposed to teeth lengthening with fixed or removable prosthodontics); and adding lip and peri-oral volume around the mouth for retention of removable prosthodontics.

There is no definitive list of therapeutic uses for Botox in the practice of dentistry. Dentists are understandably frustrated at the lack of clear guidance as to which uses are permitted under the New York licensing statute. The Education Law states only that any treatment provided by a dentist must be related to restoring or maintaining dental health. Therefore, if a dentist has questions, the dentist can and should contact the New York State Board for Dentistry, along with any professional societies, for information and guidance on whether a contemplated use falls within the practice of dentistry.5

In summary, Botox and collagen injections are valuable treatment alternatives in the practice of dentistry. However, should a dentist administer these injectables strictly for aesthetic purposes, he or she would be in violation of New York’s licensing statute and could be subject to charges of professional misconduct.

**Underwriting Note:**

Please be aware that coverage under MLMIC’s professional liability policy would be jeopardized should a policyholder practice outside what is permitted under New York law. This is not unique to MLMIC’s contract of insurance. Under New York law, no professional liability policy can cover fines and penalties related to professional misconduct, as this would be against public policy.

If you have any questions, please contact our underwriting department at one of our regional offices: NYC 1-800-683-7769; Long Island 1-888-263-2729; Syracuse 1-888-744-6729.

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5. The New York State Board for Dentistry can be reached at dentbd@nysed.gov; Telephone: 518-474-3817, ext. 550; Fax: 518-473-0567.