

Position Paper: Appropriate Use of Pharmacotherapeutic Agents by the Orofacial Pain Dentist

American Academy of Orofacial Pain

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INTRODUCTION

Orofacial Pain Dentistry is concerned with the prevention, evaluation, diagnosis, treatment, and management of persistent and recurrent orofacial pain disorders. The American Dental Association, through the Commission on Dental Accreditation (CODA), now recognizes Orofacial Pain as an area of advanced education in Dentistry. It is mandated by CODA that postgraduate orofacial pain programs be designed to provide advanced knowledge and skills beyond those of the standard curriculum leading to the DDS or DMD degrees. Postgraduate programs in orofacial pain must include specific curricular content to comply with CODA standards. The intent of CODA standards is to assure that training programs develop specific educational goals and objectives that describe the student/resident's expected knowledge and skills upon successful completion of the program. A standardized core curriculum, required for accreditation of dental orofacial pain training programs, has now been adopted.¹

Among the various topics mandated in the curriculum are pharmacology and, specifically, pharmacotherapeutics.²

The American Academy of Orofacial Pain (AAOP) recommends, and the American Board of Orofacial Pain (ABOP) requires, that the minimally competent orofacial pain dentist* be knowledgeable in the management of orofacial pain conditions using medications when indicated. Basic knowledge of the appropriate use of pharmacotherapeutics is essential for the orofacial pain dentist and, therefore, constitutes part of the examination specifications of the ABOP.

The minimally competent orofacial pain clinician must demonstrate knowledge, diagnostic skills, and treatment expertise in many areas, such as musculoskeletal, neurovascular, and neuropathic pain syndromes; sleep disorders related to orofacial pain; orofacial dystonias; and intraoral, intracranial, extracranial, and systemic disorders that cause orofacial pain or dysfunction. The orofacial pain dentist has the responsibility to diagnose and treat patients in pain that is often chronic, multifactorial, and complex. Failure to understand pain mechanisms can lead to inaccurate diagnoses and ineffective, delayed, or harmful treatment. It is the responsibility of the orofacial pain dentist to accurately diagnose the cause(s) of the pain and decide if treatment should be dentally, medically, or psychologically oriented, or if optimal management requires a combination of all three treatment approaches. Management may consist of a number of interdisciplinary modalities including, eg, physical medicine, behavioral medicine, and pharmacology or, in rare instances, surgical interventions.

Among the essential armamentarium is the knowledge and proper use of pharmacologic agents.²⁻⁴

PHARMACOTHERAPEUTICS

Pharmacotherapeutics (the study of the therapeutic uses and effects of drugs) and the appropriate use of pharmacologic agents is one of the responsibilities of the specially trained orofacial pain dentist. Comprehensive treatment of temporomandibular disorders (TMD) and chronic orofacial pain disorders requires an in-depth knowledge of many different classes of medications.

*A graduate of a 2-year, university-based, postgraduate program in orofacial pain and/or an individual who has successfully completed parts I and II of the ABOP examination.

Prior to discussion of the various medication classes used by the orofacial pain dentist, a brief discussion on pharmacokinetics is necessary.

PHARMACOKINETICS AND PHARMACODYNAMICS

Pharmacokinetics is the term used to describe interaction of a drug and the body in terms of absorption, distribution, metabolism, and excretion (ADME). In essence, the term is used as the encompassing term to describe what the organism does to the drug following exposure. Many factors influence the pharmacokinetics of a drug when a given individual patient is exposed to it. These include, but are not limited to, inborn differences in metabolic pathways, drug-drug interactions affecting ADME, and drug-disease state interactions.

Pharmacodynamics is the term used to describe the effect(s) the drug has on the organism following exposure. The effect(s) can be desirable (the intended effect) or undesirable (side effects). What is considered a desirable effect can change over time, as new knowledge is accumulated. For example, the ability of aspirin to inhibit platelet aggregation was originally considered a side effect of the drug. However, as it was demonstrated that, at lower than traditional analgesic doses, this property could be exploited to reduce the risk of stroke and myocardial infarction, a certain degree of platelet aggregation inhibition became a desirable effect.

In general, treatment of most day-to-day dental maladies is typically accomplished with local anesthetics, a narrow range of pain medications administered for a brief period, and antibiotics. Treatment or management of chronic and complex orofacial pain disorders, however, may require prolonged pharmacotherapy and the judicious use of many different types of medications, beyond those employed by the general dentist. The competent orofacial pain dentist has knowledge and understanding of many different classes of medications, including their individual pharmacokinetics and pharmacodynamics. This understanding includes the differences between oral, sublingual, rectal, parenteral, intravenous, and transdermal routes of medication administration, as well as how the route of administration affects duration of action, distribution half-life, and elimination half-life. An appreciation of the relationship of patient age to medication half-life, loading doses, maintenance doses, onset and duration of therapeutic actions and side effects, and pharmacokinetic profile (eg, peak and trough plasma levels) for any given medication is also essential.

The competent orofacial pain dentist must further understand the mechanisms of drug action, dose-response relationships, time-action relationships, and how the concepts of potency, efficacy, effectiveness, equianalgesic doses, therapeutic index, relative toxicity, number needed to treat (NNT), and number needed to harm (NNH) apply to clinical practice. In addition, because individuals with persistent orofacial pain syndromes have typically seen several practitioners in search of relief, and/or may be medically compromised, knowledge of drug interactions and how to monitor adverse drug effects is also required. As opposed to acute pain pharmacotherapy, the long-term use of med-

ications for any chronic pain condition increases the risk of adverse effects and, therefore, skillful monitoring of desired and undesired outcomes of therapy is essential.

Finally, the orofacial pain dentist has an understanding of clinical and laboratory screening tests to stratify patients according to risks and to monitor adherence to prescribed therapy; risks and diagnostic criteria for drug abuse and addiction (including ethanol, prescribed medications, nonprescribed over-the-counter and prescription medications, and illicit substances); diversion of pharmaceuticals for nonmedical purposes; and of proper counseling of patients and caregivers regarding the importance of adherence to the prescribed regimen, the importance of not sharing medications for any reason, secure storage of medicines to prevent access to children, pets, or those who may intend to divert them, and effective disposal, when medicines are no longer needed.

OROFACIAL PAIN MEDICATIONS: GENERAL PHARMACOTHERAPEUTICS⁵⁻¹²

The most common medication classes used by the orofacial pain dentist for the effective management of persistent and chronic pain are listed below. The list is not exhaustive and is not static, as new medications are constantly under research and development. In subsequent sections, each medication class will be discussed in some detail. The clinical rationale for their use, necessary information regarding these various medications, and minimum competency are elucidated, as appropriate. These drugs are used both therapeutically and, in some instances, prophylactically, based on the particular pain syndrome or side effect being managed or anticipated.

- Analgesics
- Antidepressants
- Antihypertensives (eg, beta adrenergic antagonists, calcium channel antagonists)
- Antiepileptic drugs
- Adjunctive neuropathic pain medications
- Triptans and ergot derivatives
- Anti-anxiety agents
- Muscle relaxants
- Corticosteroids
- Antihistamines
- Local anesthetics

Analgesics

Analgesics are often used for acute dental pain conditions such as pulpitis, acute periapical or periodontal abscesses, or for postsurgical pain. Short-acting opioids are frequently prescribed for treatment of these and similar dental conditions, most commonly for a relatively brief period. However, in selected cases of patients with chronic orofacial pain syndromes, longer-term opioid analgesic therapy may be appropriate to improve a patient's quality of life. When using opioid analgesics on a long-term basis, the orofacial pain dentist must follow strict guidelines for prescribing and monitoring the patient's use of these medications. (An example of a Practitioner-Patient Agreement regarding long-term opioid analgesic therapy can be found in the Appendix.)

I. Non-opioid analgesics⁵⁻¹⁶

- A. Nonsteroidal anti-inflammatory drugs (NSAIDs) and corticosteroids (antigout medications, dosing, including mechanism of action and side effects, are included in this group because of the use of NSAIDs in the treatment of arthritis)
 - 1. Role in inflammation and pain
 - 2. Classes of NSAIDs and their properties
 - 3. Effects on inflammatory mediators
 - a. Arachidonic acid cascade
 - b. Prostanoid physiology
 - c. Cyclooxygenase (COX)
 - d. Role in production of prostanoids
 - e. Prostaglandins
 - f. Thromboxane
 - g. Prostacyclin
 - h. Bradykinin
 - i. Histamine
 - j. Protons
 - k. Extracellular potassium
 - 4. Isoenzymes of COX and clinical significance (COX-1, COX-2, COX-3)
 - 5. Protective roles
 - a. Leukotriene physiology
 - b. Lipoxygenase (LOX)
- B. NSAID pharmacology—Pharmacodynamics
- C. Mechanisms of action of NSAIDs
 - 1. Interaction with COX isoenzymes, including isoenzyme selectivity profile of different NSAIDs
 - 2. Anatomic sites of actions (peripheral and central)
 - 3. Spectrum of therapeutic actions and toxicities (analgesia, platelet aggregation, temperature regulation, gastrointestinal effects, etc)
 - 4. Pharmacodynamics and pharmacokinetics of NSAIDs
- D. Common side effects of NSAIDs, especially concerning kidney, liver, gastrointestinal (GI) tract, and central nervous system (CNS)
 - 1. How NSAIDs cause GI distress regardless of the route of administration
 - 2. Which NSAIDs cause less GI distress
 - 3. Where NSAIDs are metabolized and excreted
 - 4. Minimal anti-inflammatory dosing levels
- E. Major contraindications: active ulcer disease, gastritis, renal disease, bleeding disorders, aspirin-sensitive asthma, severe hypertension, colitis
- F. Significant drug interactions involving NSAIDs/acetaminophen
- G. How to monitor long-term use of NSAIDs in regard to GI, renal, hepatic, and hematopoietic consequences
- H. Use of NSAIDs in the treatment of headache, especially indomethacin
- I. Precautions for long-term use of NSAIDs
- J. Monitoring GI blood loss
- K. Renal function
- L. Blood pressure
- M. Identification of GI controlling agents when using NSAIDs
- N. Rationale for development of specific COX-2 inhibitors and the historical development of their use in the management of acute and chronic pain conditions.
 - 1. Be cognizant of the pharmacology of celecoxib, etodolac, rofecoxib, valdecoxib, etoricoxib

- 2. Know how these drugs may lead to increased incidence of cardiovascular (CV) events and why their adverse CV effects may be more severe in patients with preexisting coronary heart disease
- O. Findings supporting a further COX subtype (COX-3) and how it may be involved in analgesia
- P. Acetaminophen
 - 1. Pharmacotherapeutics of acetaminophen, where it is metabolized and excreted, its half-life, dosing schedule, and toxicity potentials
- Q. Differences in the mode of action between NSAIDs and corticosteroids
- R. Differentiation between the mechanisms of action of NSAIDs and acetaminophen
- S. How NSAIDs and acetaminophen are similar in action.
- T. Corticosteroid pharmacology—Pharmacodynamics

II. Opioids^{7,12,15,17-19}

- A. Opioid pharmacology—Pharmacodynamics:
 - 1. Receptor pharmacology
 - a. Receptor types, subtypes, endogenous ligands, exogenous ligands, functions, full agonism, partial agonism, antagonism, and anatomic distribution
 - b. Mechanisms of actions and clinical effects of the pure agonists, agonist-antagonists, partial agonists, and the pure antagonists
 - c. Mechanisms for physical dependence
 - d. Mechanisms for tolerance
 - 2. Clinical significance of lipid solubility and molecular size (eg, use in transdermal systems, dosage estimation, intraspinal use)
 - 3. Relative potency and equianalgesic dosage conversion
 - 4. Onset of and duration of actions
 - 5. Additive and synergistic effects
 - 6. Titration and weaning
 - 7. Spectrum of toxicities, their prophylaxis and management
 - a. Respiratory depression
 - b. Chief hazard of opioid analgesics
 - c. Increased risk with opioid-disease interactions (eg, obstructive sleep apnea)
 - d. Increased risk with opioid-drug interactions (eg, benzodiazepines, antihistamines, hypnotics)
 - e. CNS depressive effects, including concomitant use with other CNS depressants (including ethanol, licit, and illicit drugs), use in head injury; seizure risk
 - f. Gastrointestinal effects, including constipation, use in pancreatic and biliary disease
 - g. Cardiovascular effects
 - h. Endocrine effects
 - i. Effects on other systems
 - j. Considerations for use in special populations (eg, pregnant women, nursing mothers, elderly, those with renal impairment)
- B. Opioid pharmacology—Pharmacokinetics
 - 1. Absorption, including differences in drug availability with different routes of administration
 - 2. Distribution, including different disease states

3. Metabolism, including variations (inborn, drug-induced) and active metabolites with analgesic efficacy or toxicity
 4. Excretion
 5. Half-lives (distribution, elimination)
 6. Time to reach steady state
 7. Single versus multiple dosing
 8. Dosing regimens (eg, time-contingent, pro re nata [prn])
 9. Clearance
- C. Pharmacological profiles of subclasses and specific opioid drug substances
1. Pure agonists
 - a. Naturally occurring (eg, morphine, codeine)
 - b. Semisynthetic (eg, hydrocodone, oxycodone)
 - c. Synthetic (eg, fentanyl, meperidine, methadone)
 2. Agonist-antagonist opioids
 - a. Mixed agonist-antagonists
 - b. Partial agonists
 - c. Pure antagonists
 3. Opioid agonists with analgesic actions in non-opioid systems: tramadol and tapentadol
 - a. Mu receptor effects of parent and metabolites
 - b. Serotonin/norepinephrine reuptake blocking effects
- D. Opioid use in different types of patients
1. Acute pain, postoperative pain
 2. Chronic cancer pain
 3. Chronic noncancer pain
- E. Abuse and addiction
1. Concepts of abuse and addiction
 2. Use of clinical and laboratory tools in assessment of risk of or presence of abuse and addiction, and adherence monitoring
 3. Epidemiology of abuse and addiction
 4. Distinctions between tolerance, physical dependence, abuse, addiction, and diversion
 5. Legal and regulatory framework for prescribing
 - a. Federal Controlled Substances Act scheduling
 - b. State scheduling of controlled substances
 - c. Statutes, regulations, guidelines, and policies affecting scope of dental practice and use of controlled substances for the treatment of pain
 6. Principles of weaning and detoxification, limits of practice for the dental practitioners (eg, DATA 2000)

Antidepressants and Anxiolytics

These drugs are used in pain management in a variety of ways. They may be used as primary analgesics in chronic pain, to manage headache and neuropathic pain, to reduce depression due to pain, and to improve the quality of sleep. Although they will be discussed to some extent in the sections on headache and neuropathic pain, their general characteristics will be outlined in this section because of their general use in pain management.

III. Antidepressants^{5-12,15,16,20-29}

- A. Types of antidepressants most commonly used in pain management
1. Tricyclic antidepressants (TCA)
 2. Serotonin specific reuptake inhibitors (SSRI)

3. Serotonin and norepinephrine reuptake inhibitors (SNRI)
 4. Monoamine oxidase (MAO) inhibitors
 5. Miscellaneous drugs to treat depression with associated disorders
 6. Others
- B. Properties of the different types of antidepressants
1. Relationship between these medications and nocturnal oral parafunctional activity
 2. Drugs that are sedating and which interfere with sleep
 3. Adverse effects: Drugs that can have significant anticholinergic side effects, can produce orthostatic hypotension, and can cause weight gain
 4. Major contraindications for each drug, eg, certain heart arrhythmias rule out the use of tricyclic antidepressants
 5. Mechanism of norepinephrine reuptake blockers
 - a. How they differ from serotonin reuptake blockers
 - b. How they are similar
 6. Dosing of TCAs in use for pain management versus use in primary depression and how to use titration to achieve therapeutic levels
 7. Primary metabolic product of nortriptyline and its mode of action
 8. Need to establish blood levels of antidepressants in establishing proper end-point doses
 9. Mechanism of action of these medications
 10. Major drug interactions with antidepressants

IV. Anti-anxiety Agents, Muscle Relaxants, Corticosteroids, Antihistamines, Local Anesthetics^{5-12,22,28}

- A. Anti-anxiety agents
1. Indications, precautions, and use of different agents
 - a. Barbiturates
 - (1) Long-, short-, intermediate-, and ultrashort-acting agents
 - (2) Use and the potential for dependency
 - b. Benzodiazepines
 - (1) Long- versus short-acting and when each is indicated
 - (2) Potential for abuse, dependence, and depression
- B. Muscle relaxants and antispasticity agents
1. Peripheral
 2. Central
- C. Corticosteroids
1. Indications and use of injectable and oral forms
 2. Systemic and local side effects
- D. Antihistamines
1. Use of these drugs in chronic pain management, especially their possible relationship to serotonin receptors in the treatment of migraine
- E. Local anesthetics
1. Use of topical and injectable anesthetics in differential blocks and in treatment of neuropathic disorders and other chronic orofacial pain conditions
 - a. When the use of concurrent epinephrine is desirable and when it is not
 - b. Amides
 - c. Esters

- (1) Differences from the amides and the indications for use, especially in trigger point injections

- F. Temporomandibular joint (TMJ) injections
1. Indications and contraindications
 2. Technique
 3. Medications

Neuropathic Pain Medications

There are indications for the use of pharmacotherapy in the treatment of chronic neuropathic pain. It is imperative to have knowledge of the laboratory studies necessary to monitor blood levels and systemic damage. The clinician must also know how to use these drugs in combination and when polypharmacy is indicated. Knowledge of the various mechanisms of action for different anticonvulsants and the implications for therapy and the concept of membrane stabilization and which anticonvulsants use this as a mechanism of action.

V. Neuropathic Pain Medications^{5-12,15,27-44}

- A. Antiepileptic drugs
- B. Antidepressants (discussed above)
- C. Alpha blockers
1. Oral, injectable, and skin patch forms of these drugs
 2. Use for diagnosis and treatment of neuropathic pain
 3. Mechanism of action and side effects
 4. Alpha-1 versus the alpha-2 receptor types
 - a. How this affects the antagonist chosen
- D. Miscellaneous medications
1. Local anesthetics in oral form in the treatment of chronic pain
 2. Use of topical formulations in treating neuralgias (eg, capsaicinoids, local anesthetic patches, etc)
 3. Neuroleptics (antipsychotic drugs)
 4. Side effects that these drugs may produce, eg, tardive dyskinesia, Parkinsonism, dystonia, and akathisia
 5. Use in combination with the anticonvulsants
 6. Familiarity with the advantages and disadvantages in comparison with the anticonvulsants (discussed in section VI)
- E. Analeptic drugs
1. The current literature supports the analgesic properties of drugs such as dextroamphetamine
- F. Understanding the concepts of surgical therapy for neuropathic pain

Preventive/Prophylactic Drugs

A variety of chronic pain conditions, such as neurovascular orofacial pain, may require continuous prophylaxis to maintain quality of life. In these cases, the chronic use of medications to eliminate or minimize pain states requires the same vigilance as does the chronic use of neuropathic medications discussed above. However, different classes of medications are employed, which may include triptans, calcium channel and beta blockers, as well as the judicious use of NSAIDs and analgesics.

VI. Commonly Used Preventive/Prophylactic Drugs For Head and Face Pain Syndromes^{5-12,27-30,45-53}

- A. Indications for use of preventative medications
1. More than one severe headache per week that does not respond to nonpharmacologic treatment
 2. The severity and duration of the attack justifies the use of preventive treatment
 3. Symptomatic medication is not effective for infrequent headaches
 4. Symptomatic treatment is contraindicated because of medical problems
 5. To enhance the effectiveness of a symptomatic medication
- B. Medications used for prevention
1. Beta adrenergic blockers may be used in migraine prophylaxis
 2. Proposed mechanism of action of beta blockers in the treatment of migraine
 - a. Inhibition of norepinephrine release
 - b. Delayed reduction in tyrosine hydroxylase activity
 - c. Delayed reduction of locus ceruleus neuron firing rate
 - d. Possible cross-modulation of the serotonin system
 3. Side effects and contraindications of beta blockers, as well as their dosage forms, and areas of recommended use
 4. Use of calcium channel blockers in the prophylaxis of migraine
 5. Proposed mechanism of action for the calcium channel blockers
 - a. Blocking of 5HT release
 - b. Interference with neurovascular inflammation
 - c. Interference with spreading depression
 - d. Inhibition of contraction of smooth muscle
 - e. Inhibition of calcium-dependent enzymes involved in prostaglandin synthesis
 - f. Influence on serotonin systems
 - g. Prevention of hypoxia on cerebral neurons
 6. Side effects, contraindications, dosage forms, and areas of recommended use of calcium channel blockers
 7. Use of TCAs and other antidepressants in migraine prophylaxis (discussed above)
 8. Use of ergotamines for migraine prophylaxis
 9. Metabolic byproduct of methysergide (methyl-ergonovine), available as Methergine
 - a. Side effects, especially retroperitoneal fibrosis, and the special dosing regimens with "vacations" from the drug
 10. Use of anticonvulsants in the prophylaxis of migraine
 11. Other drugs sometimes used in prevention of migraines
 12. Length of time necessary to maintain a patient on a particular preventive and at what dose before you judge it to be ineffective and try another preventive
- C. The role of serotonin and 5HT receptor sites in migraine prophylaxis
1. The differences between receptor sites in prophylaxis versus abortive treatment with ergotamines
 2. Indications for abortive medications versus prophylactic medications

- D. Most common medications used for abortive treatment of migraine and cluster headache
1. Analgesics
 - a. Use of analgesics for headache and when to avoid their use
 - b. Role of indomethacin in the treatment of chronic paroxysmal hemicrania
 2. 5HT agonists
 - a. Ergotamines
 - (1) Potential for use of CGRP antagonists in migraine treatment
 - (2) Potential for use of memantine in migraine treatment (often used as a preventative medication)
 3. Common symptomatic medications used to treat migraine and cluster headache
 - a. Opioids (discussed above)
 - b. NSAIDs (discussed above)
 - c. Antiemetics
 4. The concept of analgesic rebound headache (certain symptomatic medications taken excessively can potentiate some headaches)
 - a. Agents that can potentially cause analgesic rebound
 - (1) Caffeine
 - (2) Benzodiazepines
 - (3) Opioids
 - (4) Ergots
 - (5) Barbiturates (eg, butalbital)
 5. Corticosteroids (discussed above)
- E. Medications most commonly used for tension-type headache (TTH)
1. Analgesics (discussed above)
 2. Muscle relaxants (discussed above)
 3. Combination drugs
 - a. Availability
 - b. When indicated
 4. TCAs (discussed above)
 5. Other anti-migraine drugs (discussed above)

REGULATIONS AND COMPLIANCE

The Drug Enforcement Administration (DEA), through their Office of Diversion Control (Diversion), is responsible for enforcing federal laws and regulations pertaining to manufacturing, distribution, and dispensing of Schedules II through V controlled substances. The DEA regulations pertaining to the prescribing of controlled substances as part of a pain management treatment plan are covered under Title 21, Code of Federal Regulations Section 1306.

The role of DEA Diversion is to assure the public that any controlled substance that is administered, dispensed, or prescribed by a health care professional is done for a legitimate medical purpose by a DEA-registered practitioner acting in the usual course of their professional practice. The term “practitioner” has been defined as a physician, dentist, veterinarian, or any other health care professional licensed by a state and registered with DEA who is authorized to prescribe, dispense, and administer a controlled substance in the usual course of their professional practice. The DEA also enforces the “cor-

responding responsibility” obligation of the pharmacist who dispenses a prescription for a controlled substance.

Many pain-management physicians have realized that the pain suffered by patients with chronic orofacial pain would require the patient to be evaluated and treated for their pain by a specialist in the field of orofacial pain dentistry. In those cases, the pain-management physicians will not treat a patient suffering with chronic orofacial pain since the physician may consider it to be outside of their professional practice. On the other hand, law enforcement and regulatory entities, including DEA, may not be familiar with the field of orofacial pain dentistry and will treat any prescription with the suspicion that the prescription may not be for a legitimate medical purpose.

Dentists practicing in the area of chronic orofacial pain should familiarize themselves with federal/state laws and regulations pertaining to administering, dispensing, and prescribing of a controlled substance to a patient as part of a pain-management treatment plan for chronic orofacial pain.

Documentation in a patient chart is necessary when treating chronic orofacial pain and such documentation is required by most state dentistry boards. This should include:

- Initial patient evaluation
- Patient's medical history
- Referral letters from the primary care provider
- Medical tests and pain evaluations
- Evaluation of level of pain
- Patient agreement and drug screening
- Listing of prescribed medications

Any questions from law enforcement and regulatory entities with regard to administering, dispensing, or prescribing controlled substances should be resolved by a well-established dentist-patient relationship and the documentation from a patient chart listing the findings of the patient's condition, with the treatment plan requiring the administering, dispensing, or prescribing of a controlled substance necessary to treat the chronic pain. Office procedures for prevention of diversion of prescribed medication by substance abuse patients should be developed by dentists treating chronic orofacial pain.

Information on federal laws and DEA regulations pertaining to the administering, dispensing, and prescribing of Schedules II through V controlled substances can be found on the DEA Diversion website at <http://www.deadiversion.usdoj.gov>.⁵⁴

APPENDIX

Informed Consent and Controlled Substance Agreement for Treatment of Chronic Orofacial Pain

_____ date

This is an agreement between _____ and Dr _____
(please print your full name and date of birth)

I, _____ (please print your full name), understand and agree to follow the regarding the use of controlled substances (opioids or narcotics) for management of chronic pain as set forth below. I understand that **Dr _____ is under no obligation to prescribe these medications for me.** I also understand that breaking this contract may lead to the termination of this contract or my dismissal from treatment.

I have tried other medical and dental treatments which have not worked to control my chronic orofacial pain. Dr _____ has recommended that I be placed on a course of medications to help manage my pain better and to improve my ability to participate in my activities of daily living (work, family, etc). I also understand that these medications are not expected to entirely eliminate all pain, but are intended to help me to improve my quality of life. This is a decision that I have made after fully discussing the risks and benefits of this treatment, as well as alternatives to this treatment, with Dr _____.

Risks:

I understand that treatment of pain with opioids does have risks including, but not limited to:

- Breathing too slowly, losing the urge to breathe, or loud snoring may mean that the medicine is interfering with the part of the brain that controls breathing. This is the major risk of these medicines and can lead to stopped breathing and death. I understand that it is recommended that I wear an emergency alert bracelet or necklace with language stating I am taking this medication.
- Constipation and/or nausea.
- Sleepiness or drowsiness.
- Problems with coordination or balance that may make it unsafe to operate dangerous equipment or vehicles, or to cook and perform various tasks at work.
- Confusion or other change in mental state or thinking abilities.
- Physical dependence—meaning that abrupt discontinuation of the drug may lead to withdrawal symptoms including: runny nose, diarrhea, abdominal cramping, “goose flesh” and/or anxiety, etc. I understand that this may be uncomfortable but not life threatening and the worst symptoms typically resolve after 72 hours.
- Addiction—meaning it is possible that discontinuation of the drug may cause me to miss it or crave it, or that I could begin to have problems controlling my use of the medicine.
- Decreased appetite.
- Problems urinating.
- Sexual difficulties.
- Known and unknown risks to unborn and nursing children, which includes opioid dependence. Contraception is highly recommended.
- Other less common risks and side effects are possible.

Conditions:

Dr _____ is willing to begin or continue treating me with opioids under the following conditions that I have accepted:

1. Other acceptable forms of medical treatment have not been effective or have produced undesirable side effects. _____ (initials)
2. I currently do not have problems with substance abuse, illegal drugs, or drug dependence. _____ (initials)
3. I am currently not involved in the sale, illegal possession, diversion, or transport of controlled substances (narcotics, sleeping pills, nerve pills, or painkillers), nor do I live or associate with individuals who do. I will disclose to Dr _____ any past involvement in the sale, illegal possession, diversion, or transport of controlled substances. _____ (initials)
4. I agree to obtain opioid prescriptions only from Dr _____. I agree to notify Dr _____ in advance of any acute needs (ie, dental work, surgery) that may necessitate a change in my opioid dose. _____ (initials)
5. I will use **only** _____ Pharmacy for filling of prescriptions for opioids and other controlled drugs. _____ (initials)

I have read this document, understand it, and have answered all questions satisfactorily. I consent to the use of these medications to help control my pain, and I understand that my treatment with these medications will be carried out in accordance with the conditions stated above.

I agree that a copy of this document will be given to my pharmacist, my primary care physician, and to all other health care providers involved with my healthcare. I will keep Dr _____, my pharmacist, and all my health care providers informed at all times of all medications that are being prescribed for me. Full disclosure is mandatory.

Primary care physician: _____

Phone number: _____

Address: _____

Other provider: _____

Phone number: _____

Address: _____

Other provider: _____

Phone number: _____

Address: _____

Other provider: _____

Phone number: _____

Address: _____

Patient's signature _____ Date _____

Witness _____ Date _____

Doctor's certification: I certify that the above named patient or responsible individual has received a careful explanation of the treatment to be provided, including the risks and benefits to be expected. I have disclosed alternative methods of pain management that might be appropriate for this patient. I have offered to answer any questions by this patient and/or responsible individual regarding this treatment.

Doctor _____ Date _____

In an effort to assure that your prescription will be filled in a timely manner, our office is requiring that all requests for refills be made at least _____ business days in advance of the refill date. Please leave your first and last name, your phone number, and your date of birth. Also provide the name of the medication, the dose, and the quantity needed, as well as the name and phone number of your pharmacy.

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