

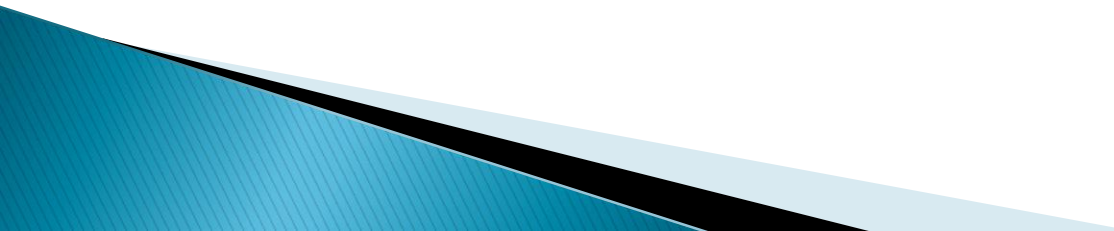
# Regulatory and Legal Issues arising from Grey Market Dental Products

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# Risks of Using Grey Market Dental Products.

- ▶ Risk of being charged with professional misconduct by the Royal College of Dental Surgeons.
  - ▶ Risk of potential civil liability in a malpractice claim.
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# Professional Misconduct Issues.

- ▶ Using a Grey Market dental product is likely a breach of the standards of practice of the profession.

2. The following are acts of professional misconduct:

1. Contravening a standard of practice or failing to maintain the standards of practice of the profession.

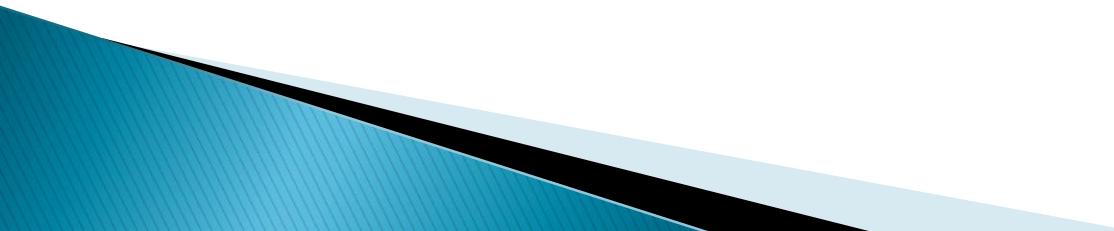
# Professional Misconduct Issues. (con't.)

- ▶ Depending on the factual circumstances, a dentist could also be charged with disgraceful and dishonourable conduct, which is another act of professional misconduct under the *Dentistry Act*.

59. Engaging in conduct or performing an act that, having regard to all the circumstances, would reasonably be regarded by members as disgraceful, dishonourable, unprofessional or unethical.

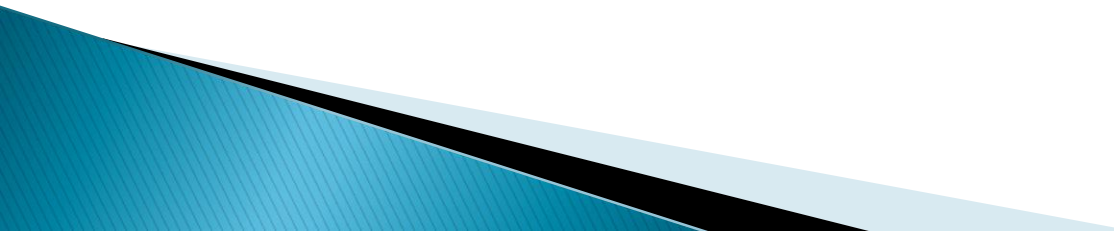
- ▶ The RCDS typically utilizes the “disgraceful and dishonourable” provision where there is an element of intentional misconduct or moral turpitude.

# Professional Misconduct Issues. (con't.)

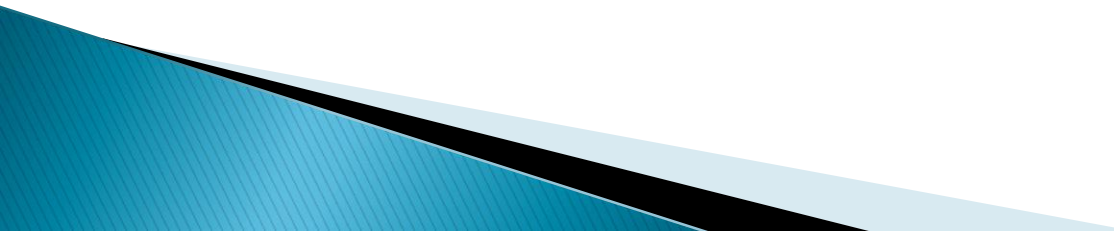
- ▶ The majority of standards of practice prosecutions at the RCDS are not based on a breach of a specific regulation.
  - ▶ There is no specific provision addressing the use of Grey Market products.
  - ▶ The RCDS will prove a failure to maintain the standards of practice allegation, through an expert opinion that a prudent dentist would not use a Grey Market dental product.
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# Factual scenarios concerning use of Grey Market dental products.


## First Factual scenario:

- ▶ A dentist inadvertently purchases Grey Market dental products.
  - ▶ The dentist can prove that she has exercised due diligence in a manner in which her dental practice purchases supplies.
  - ▶ The dentist has adopted the following procedures in her office:
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# Factual scenarios concerning use of Grey Market dental products. (con't.)

- ▶ She contacts the manufacturer to determine who the authorized dealers are for the dental products she uses in her dental practice.
  - ▶ She maintains a list of products licensed for sale in Ontario.
  - ▶ The dentist checks her supplies before they are used in the operator, looking for expiry dates, unfamiliar packaging or any suspicious circumstances.
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# Factual scenarios concerning use of Grey Market dental products. (con't.)

- ▶ If a dentist can prove that she took all these steps, and yet still inadvertently purchased Grey Market dental products, then it is arguable that the dentist would not be guilty of professional misconduct.
  - ▶ If the dentist can satisfy the RCDS she had taken all reasonable steps, then it would be unlikely that the Investigation, Complaints and Reports Committee (the “ICRC”) of the RCDS would refer the matter for a discipline hearing.
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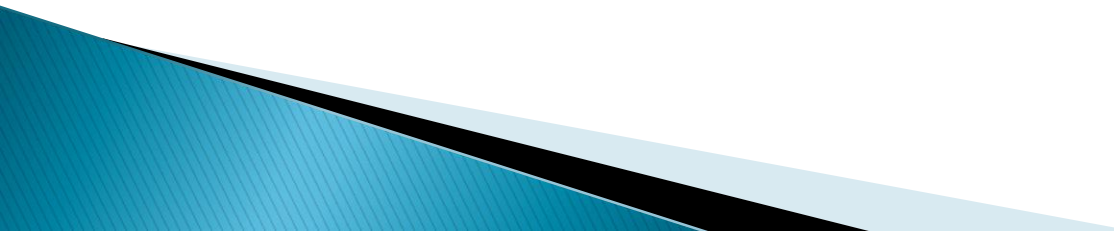


# Factual scenarios concerning use of Grey Market dental products. (con't.)


- ▶ This is because the ICRC would conclude the dentist met the appropriate standards of practice demanded of her.

# Factual scenarios concerning use of Grey Market dental products. (con't.)

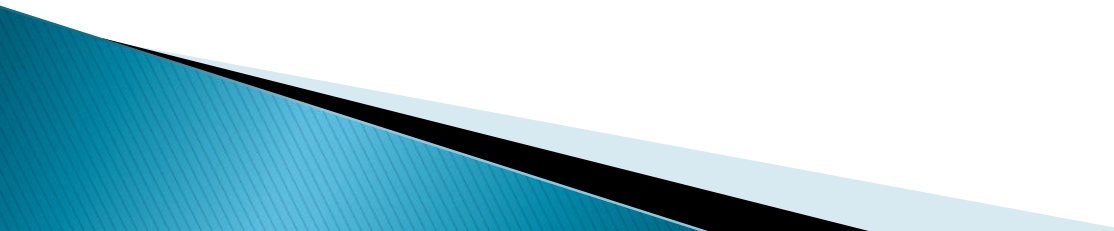
## Second Factual Scenario:

- ▶ A dentist is negligent with respect to sourcing and purchasing dental supplies.
  - ▶ The dentist has no due diligence measures, and urges her staff to purchase dental supplies from dubious sources for the cheapest prices.
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# Factual scenarios concerning use of Grey Market dental products. (con't.)

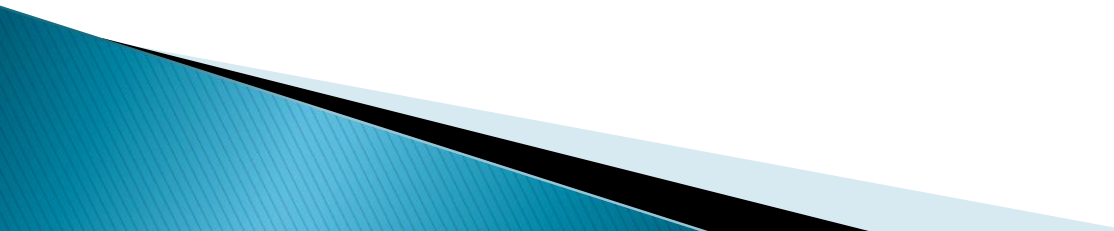
- ▶ If a patient complained, or if the RCDS investigated, then this dentist may be referred to the Discipline Committee and prosecuted for failing to maintain the standards of practice of the profession.
  - ▶ We assume that the RCDS could locate a GP dentist expert who would testify that a prudent dentist should always be mindful of ensuring that dental supplies purchased are appropriate and legal.
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# Factual scenarios concerning use of Grey Market dental products. (con't.)

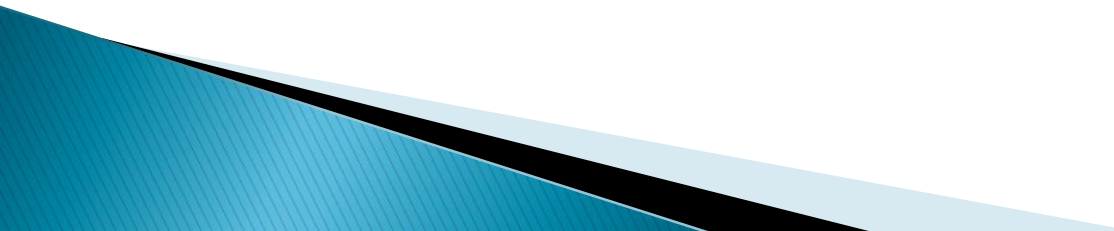
- ▶ The dentist would be unable to prove due diligence, and would likely be convicted of failing to maintain the standards of practice of the profession by not having appropriate systems in place to ensure that dental supplies used in her practice are appropriate for the purpose.
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# Factual scenarios concerning use of Grey Market dental products. (con't.)

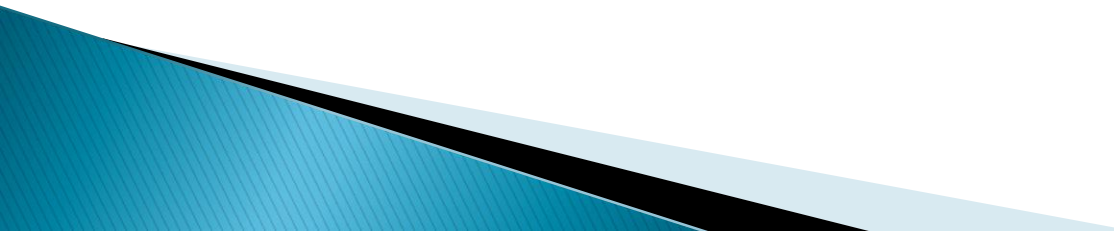
## Third Factual Scenario:

- ▶ Assume that the dentist deliberately and knowingly purchases Grey Market supplies for a cheaper price than the official price.
  - ▶ Assume that a patient suffers adverse physical consequences as a result of the use of the grey market supplies.
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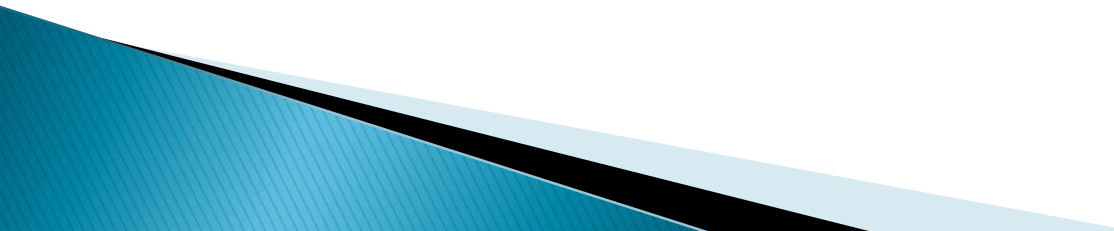
# Factual scenarios concerning use of Grey Market dental products. (con't.)

- ▶ In this hypothetical, the dentist would likely face prosecution for failing to maintain the standards of practice of the profession, and disgraceful and dishonourable conduct.
  - ▶ The intentional efforts to save money and purchase illegal supplies would be looked upon poorly by the Discipline Committee.
  - ▶ The intentional disregard for patient safety would engage the “disgraceful and dishonourable” particular of professional misconduct.
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# Factual scenarios concerning use of Grey Market dental products. (con't.)

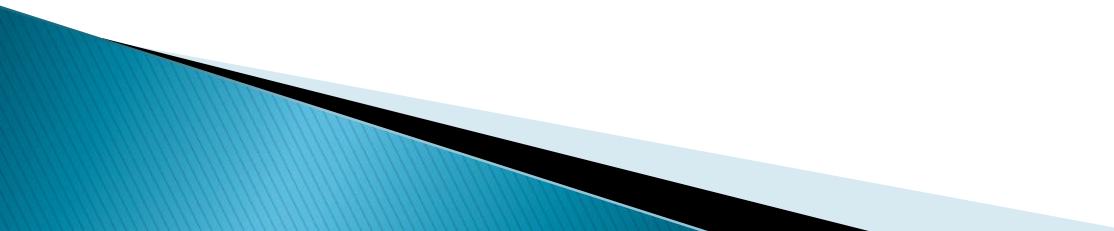
- ▶ Disciplinary Tribunals tend to punish intentional wrongdoing more harshly than mere negligence or sloppiness.
  - ▶ On these facts, the Discipline Committee may be obliged to suspend the dentist's license for a period of time.
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# Factual scenarios concerning use of Grey Market dental products. (con't.)

- ▶ This is because the dentist's dishonesty and improper financial motives led directly to an adverse outcome.
  - ▶ It is the element of intentional misconduct that will raise the ire of a Discipline Committee.
  - ▶ An analogy can be made to insurance fraud.
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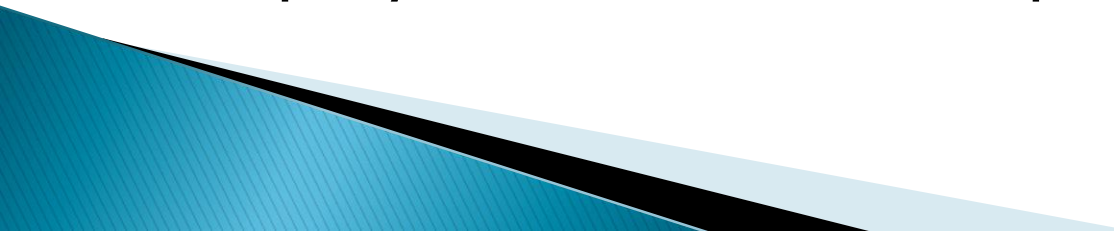
# How do you avoid RCDS difficulties arising from Grey Market dental products?

- ▶ Adopt a system of due diligence with respect to the purchase of dental supplies and products.
  - ▶ Dentists should keep the necessary documents to prove due diligence.
  - ▶ A check list of steps to be taken in the office on a monthly basis could assist in proving that a due diligence system was in place.
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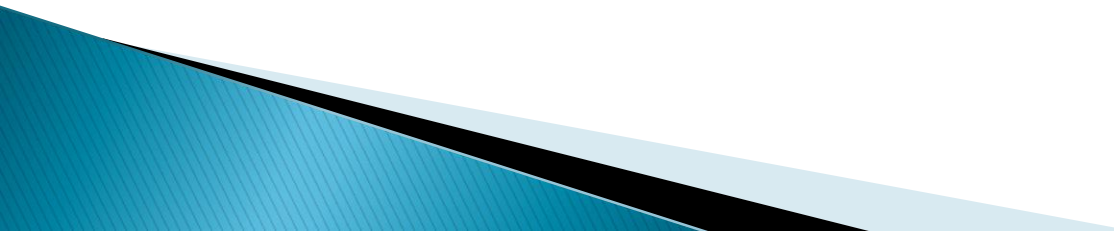
# Considerations for Associates

- ▶ Typically an associate will have no role in sourcing and ordering dental supplies.

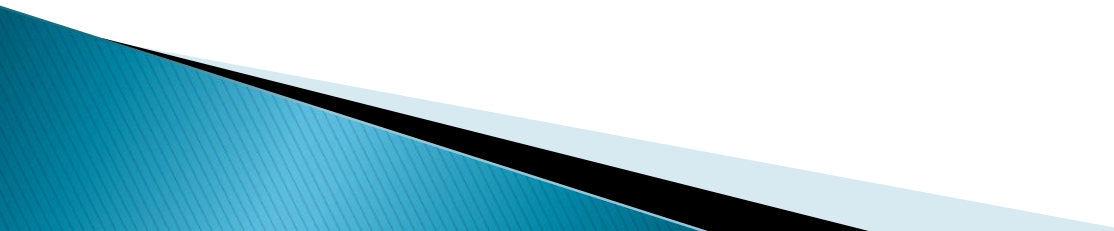
# What can an Associate dentist do to fulfill his or her obligations to ensure that no Grey Market products are provided to patients?

- ▶ Communicate in writing with the Principal to ascertain what safeguards are in place to ensure that, deliberately or inadvertently, Grey Market products are not being used in the practice.
  - ▶ If the Associate is concerned about the response that is received, or if there no system, then the Associate should have a written record of the inquiry made to the Principal.
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What can an Associate dentist do to fulfill his or her obligations to ensure that no Grey Market products are provided to patients? (con't.)

- ▶ The Associate should suggest that basic due diligence processes be adopted.
  - ▶ If the Principal refuses, then the Associate should adopt his or her own measures to rule out the possibility of using unsafe products and supplies.
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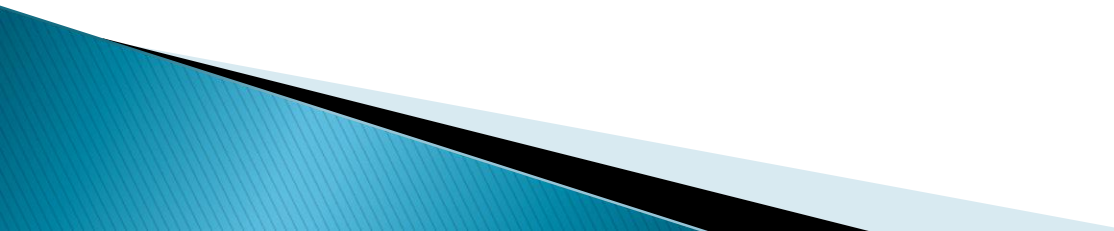
# Civil Liability issues arising from the use of Grey Market dental products.

- ▶ All Ontario dentists are obliged to maintain mandatory malpractice insurance.
  - ▶ Malpractice insurance contains an exclusion in respect of certain types of damages.
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# Exclusions to the Insured's Coverage – Excerpt from PLP Malpractice Policy

- ▶ Subject to the balance of the provisions of this **PART**, this **POLICY** does not apply:
  - f) to:
    - (i) fines,
    - (ii) penalties,
    - (iii) punitive, aggravated, exemplary or similar damages; or
    - (iv) any sum for which insurance is forbidden by law

# Factual Scenario


- ▶ A dentist has deliberately used Grey Market dental supplies which defective product causes pain and suffering for the patient;
  - ▶ The patient sues the dentist for dental malpractice;
  - ▶ The malpractice insurer defends;
  - ▶ The Plaintiff's claim includes a claim for punitive damages.
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# Factual Scenario (con't.)

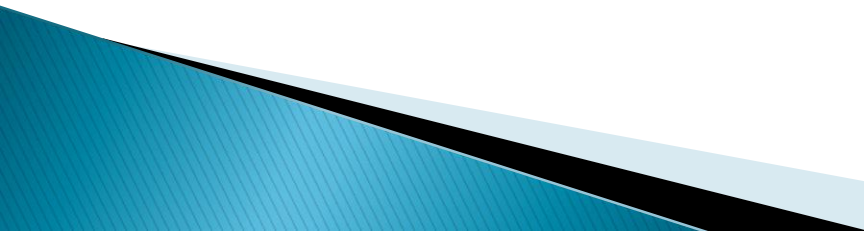
- ▶ Punitive damages are rarely awarded by Courts, and are designed not to be compensatory in nature, but to indicate the displeasure of the Court, and to punish.
  - ▶ The purpose of an award of punitive damages is to demonstrate to the offender that the law will not tolerate conduct that wilfully disregards the rights of others.
  - ▶ In health law, Courts have awarded damages for battery, where a patient fails to provide an informed consent before a health professional performs physically intrusive treatment on the patient.
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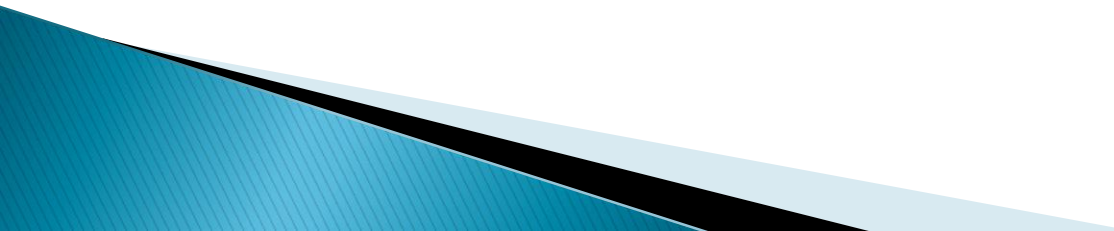
# Factual Scenario (con't.)

- ▶ Assume a factual scenario where the dentist advises her patient that she will be receiving implants of the highest quality, and yet knowingly uses grey market implants that turn out to be defective.
  - ▶ On these facts, the dentist has likely committed a battery on the patient.
  - ▶ The patient would not have consented to procedure if the dentist had disclosed that the implants being used were Grey Market implants.
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# Factual Scenario (con't.)

- ▶ In a 1985 Ontario Court of Appeal decision in *Gerula v. Flores*, a punitive damages award of \$40,000.00 was imposed against a physician where the physician had deliberately altered medical records to conceal the fact that an operation that was performed on a patient was unnecessary. The Court found that there was a battery, and that the physician's acts "were motivated by self interest detrimental to the patient's interest".
  - ▶ If a patient can prove that a dentist knowingly used Grey Market dental products, then the malpractice lawsuit would include a claim for punitive damages.
  - ▶ Your malpractice insurer would not provide coverage for these punitive damages claims.
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# Factual Scenario (con't.)

- ▶ You would be obliged to retain separate legal counsel to deal with that aspect of the case.
  - ▶ If punitive damages were awarded at trial, the dentist would have to pay those damages herself.
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# Criminal Consequences.

- ▶ There is no reported case in Canada where a dentist has been criminally prosecuted for using Grey Market dental products.
  - ▶ However, a deliberate purchase of the Grey Market dental products and a misrepresentation to the patient would likely be considered criminal fraud.
  - ▶ In theory it is possible that a dentist could be criminally prosecuted for using Grey Market dental products.
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