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ETHICAL AND LEGAL ASPECTS OF THE USE OF FAKE DRUGS FOR OROFACIAL AESTHETICS – A CASE REPORT.

Aspectos éticos e legais do uso de medicamentos falsos para a estética orofacial – relato de caso.

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ABSTRACT

Introduction: Over the last decade, Botulinum Toxin (BT) gained space in the armamentarium of drugs used for orofacial aesthetics. The contemporary scenario of Dentistry led to new horizons within aesthetic treatments founded on the application of BT. **Objective:** This study aimed to report a case of fake type-A BT sold to a dentist on training for orofacial aesthetics. **Material and methods:** During a 16-hour training course, a dentist bought from a reference seller a “so-called” quality drug allegedly consisting of type-A BT. After suspecting of fake drug based on uncommon label and flask, the dentist sent images of the product to the laboratory responsible for registering the drug at the National Health Surveillance Agency (ANVISA). **Results:** The laboratory confirmed the fake drug. ANVISA blocked the commercialization, use and distribution of the product as well as made efforts to remove the available products from the market. Parallel police investigations were carried out and forensic expertise for drug profiling was accomplished – confirming the fake drug. **Conclusion:** This study drives attention to the possibility of existing fake drug commercialization to dentists dedicated to orofacial aesthetics, and the potential impact of this drugs if used in patients. Consequences might extend to penalties in the consumer relation interface, as well as in the criminal field as offense against public health.

KEYWORDS

Botulinum toxin; Drug; Ethics; Forensic dentistry.

INTRODUCTION

Following technical and scientific development, the functional and aesthetic properties of Botulinum Toxin (BT) entered

the spotlight of science. Applications transcended from intramuscular injection for the treatment of spasticity¹ to corrective use for minimizing signs of aging². Type A BT

(specifically commercialized in health sciences) became a popular drug in Medicine. Its biochemical effects manifest by directly blocking muscular activity at synaptic level and temporarily hampering contraction³. The clinical benefits of this drug gradually raised the attention of dentists.

Brazil is ranked together with countries that host highest numbers of dentists worldwide⁴. Orofacial aesthetics emerged as a promising field in recent dental history in the country⁵. TB use found in this scenario an expanding niche. In Dentistry, TB-based therapeutics include the correction of gummy smile⁶, treatment of bruxism⁷, improvements to orthodontic treatment⁸ and temporomandibular disorders⁹. Aesthetic applications, however, currently represent one the most popular interest among professionals that adhere to this trend.

Counterbalancing this phenomenon, the risk of acquiring and administering fake drugs exists – especially because TB is an unusual product, mainly for less-experienced professionals in the field of orofacial aesthetics. Based on the importance of highlighting the ethical and legal aspects of drug acquisition and administration in Dentistry, the present study aimed to report a case of fake TB bought by a young dentist from an alleged reference seller, during a short course training dedicated to orofacial aesthetics.

CASE REPORT

In 2017, a short course on facial fillers was provided to dentists. The course

had 16 hours and was carried out in two days in Central-Western Brazil.

In the last day of the course, an alleged reference seller approached the students offering type A BT with Botox™ (Allergan Ltd.™, Dublin Ireland) label. The drug was offered at US 116.00 (American dollars - nearly R\$ 580,00 Brazilian reais) – under the usual commercial price. The same drug used along the course, even in patients that volunteered for aesthetic treatment.

One of the students bought six flasks of the product. After showing the drug to a colleague outside the course, suspicion emerged as the label and flask were uncommon (Figure 1). Specifically, the label clearly informed “*Botulinum Toxin Type A*”, serial code C3239C3 and expiration date of February 2020. The invoice provided by the seller only informed “surgical product”.

The student contacted the Brazilian representative of the Botox™ drug and provided images to be analysed by the company. Internal investigation confirmed the fake product, especially because the serial code was never registered in the company. The Brazilian National Surveillance Agency (ANVISA) was notified in January 2018 and released the Resolution #115/2018 published in Union’s Official Diary (Figure 2). The resolution prohibited the distribution, commercialization and use of the fake drug as well as seizure of the products with the serial code # C3239C3.



Figure 1 – Posterior (A) and anterior (B) views of the product bought during the short course compared to the official type A BT (C).

RESOLUÇÃO-RE Nº 115, DE 12 DE JANEIRO DE 2018

A Gerente-Geral de Inspeção e Fiscalização Sanitária, Substituta, no uso das atribuições que lhe foram conferidas pela Portaria nº 1.959, de 24 de novembro de 2017, aliado ao disposto no art. 54, I, § 1º da Resolução da Diretoria Colegiada - RDC nº 61 de 3 de fevereiro de 2016;

Considerando o art. 62, caput e item II, da Lei nº 6.360, de 23 de setembro de 1976;

Considerando o art. 7º, XV, da Lei nº 9.782 de 26 de janeiro de 1999;

Considerando que a empresa Allergan Produtos Farmacêuticos Ltda., detentora do registro do medicamento BOTOX 100 U (toxina botulínica), pó liofilizado, identificou a falsificação do mesmo por apresentar características divergentes daquelas registradas na Anvisa e não sendo os mesmos de procedência da empresa, resolve:

Art. 1º Determinar, como medida de interesse sanitário, a proibição da distribuição, comércio e uso, bem como a apreensão e inutilização, em todo o território nacional, do medicamento BOTOX 100 U (toxina botulínica), pó liofilizado, lote C3239C3, tendo em vista que o mesmo não é procedente do laboratório Allergan Produtos Farmacêuticos Ltda., tratando-se, portanto, de falsificação comprovada.

Art. 2º Esta Resolução entra em vigor na data de sua publicação.

MARIÂNGELA TORCHIA DO NASCIMENTO

Figure 2 – ANVISA resolution published in Union's Official Diary.

Police investigation was conducted by the local authorities. The case was founded on potential crime against consumer's interests. The crime was inherent to Article 273 § 1st B-I of the

Brazilian Criminal Code, which describes crime of fake products for medical therapeutics, and Federal Law 8.137/1990, which describes crime within consumer relations.

Forensic expertise was requested during police investigation to answer the following questions: 1) what are the characteristics of the flask and label of the product, its serial number, date of manufacture and date of expiration?; 2) Was the product registered in the Brazilian National Surveillance Agency? 3A) By means of qualitative analysis, is it possible to state that the product is altered, fraudulent or dangerous to human health? 3B) Is it presented according to regular standards of manufacture, distribution and presentation? 3C) Is it presented with reduced therapeutic value? 3D) Is it presented without identifying information and necessary data for commercialization? 4) Is the product legitimate?

The Brazilian representative of the company provided a sample of the original product as reference for comparative forensic analysis. All the photographs obtained from the flasks were provided to support the analyses and official forensic report. The differences pointed by the experts in the report consisted of the use of vernacular language used in the reference flasks but not used in the questioned product; different font used between reference and questioned materials; and metallic protection with different shapes. Laboratory analyses were not feasible due to lack of available facilities. However, the forensic report concluded by confirming the fake product via qualitative macroscopic external analysis of the flasks.

DISCUSSION

Knowing product-specific characteristics and instructions provided by

the manufacturer is essential in any field of Dentistry^{10,11}. When it comes to Ethics, recent regulations built-up a scenario for dental practice with BT-based products. Over the last eight years, the Brazilian Federal Council of Dentistry released several resolutions that addressed the limits of technical procedures. Resolution #112/2011 prohibited the use of BT for procedures that were exclusively related to aesthetics and allowed the use for therapeutic dental procedures¹². Three years later, resolution #145/2014 maintained the use of BT in Dentistry when justified for therapeutic needs¹³. A month later, resolution #146/2014¹⁴ deemed the matter more obscure by modifying the previous resolution, adding the following text (adapted from Portuguese): “*BT is allowed for dental procedures and prohibited for non-dental procedures*”. In 2016, resolution #176/2016 replaced the previous by stating that BT is allowed in Dentistry for aesthetic and functional therapeutics if used within the anatomic limits of dental practice¹⁵. The same resolution describes as anatomic limits for dental practice the region between the hyoid bone and Nasion, and anteriorly to the tragus¹⁵. For non-surgical procedures dedicated to facial harmonization, the upper third of the face was included¹⁵.

The aesthetic applications authorized by the Brazilian Federal Council of Dentistry, combined with the Brazilian Federal Law 5.081/66 (that authorizes the use of dental knowledge acquired during undergraduation and graduation courses)¹⁶, triggered the interest of many dentists. Consequently, several courses were designed and offered to dentists that were

seeking for training. Among these courses, short ones spread over the country made training accessible but not necessarily efficient. These courses were more common before the regulation of orofacial aesthetics as dental specialty. The case reported in this study illustrates the lack of proper selection of sale representatives of BT drugs and brands that affected some of these courses (not generalizing, as it depends on course coordination and structure). These limitations might reflect on students that will not be able to perform in practice with ideal skills – especially if they were trained with non-ideal drugs.

Studies highlight the fact that counterfeit drugs are dangerous by themselves, but fake BT-based drugs are even more dangerous because the main substance of the drug represents a deadly poison¹⁷. So, the present study raises the following question: “what happens if you give a deadly poison (manifested as fake drug) to a dentist trained for aesthetic applications over a two-day course?” Clearly, a threat to public health is depicted. In order to control the scenario and promote best practices, courses on orofacial aesthetics were better structured in Brazil, under the umbrella of dental specialty. According to Federal Council of Dentistry’s resolution #198/2019⁵, specialization courses on orofacial harmonization must have at least 500 hours. This aspect of the course program enables students to pursue stronger knowledge in the field, especially in relation to pharmaceuticals and drug

administration. Despite the advances on formal training, the development of knowledge and skills will depend individually on the dentist and his/her ability to develop the predicted competencies of the specialty.

Clinical effects of fake drug administration might include allergies, necrosis, scars and facial deformation. Dentists must be aware of these effects because patients that seek for aesthetic improvement do not wish the opposite. Finding the best training and investigating the origin of medication offered during the course for application in patients are the very first steps towards safe practices in facial aesthetic procedures. Dentists must be aware of the opportunistic courses and drug sellers that see orofacial harmonization as a source of clients that ingenuously buy medication with uncertain description/origin.

FINAL CONSIDERATIONS

Counterfeit drugs subtly entered the dental market. Opportunistic courses with non-verified drug representatives and sellers took this chance to offer products below the average price. BT figures a drug of interest of many dentists in Brazil, especially among those ongoing training in orofacial aesthetics. Originally, BT is a deadly poison. The drug itself may be a weapon in wrong hands. Consequently, counterfeit BT may be even worse. Dentists must be aware of their choice for training in the field, as well as for the origin of drugs bought along the course.

RESUMO

Introdução: Ao longo da última década, a Toxina Botulínica (TB) ganhou espaço no rol de ferramentas utilizadas para a estética orofacial. O cenário odontológico contemporâneo levou a novos horizontes frente a tratamentos estéticos fundamentos na aplicação de TB. Objetivo: O presente estudo objetivou reportar um caso de TB tipo A falsificada adquirida por Cirurgião-dentista que cursava treinamento em estética orofacial. Materiais e métodos: Durante curso de 16 horas de duração, um cirurgião-dentista adquiriu um medicamento supostamente vendido como TB do tipo A. Ao suspeitar do produto pela aparência incomum do seu rótulo e frasco, o profissional enviou imagens para o laboratório responsável pelo registro do mesmo frente à Agência Nacional de Vigilância Sanitária (ANVISA). Resultados: O laboratório confirmou a falta de autenticidade do produto. Neste sentido, a ANVISA proibiu a comercialização, o uso e a distribuição do produto, e determinou sua apreensão e retirada do mercado. Inquérito policial paralelo foi instaurado e pericia de natureza oficial foi conduzida – confirmando a falsidade da droga. Conclusão: Este estudo ressalta a possibilidade da existência de comercialização de drogas falsas para cirurgiões-dentistas dedicados à práticas estéticas orofaciais, e o potencial impacto dessas drogas caso administradas aos pacientes odontológicos. As consequências inerentes podem se estender a penalidades na interface consumerista, assim como à esfera penal como crime contra a saúde pública.

PALAVRAS-CHAVE

Toxina botulínica; Droga; Ética; Odontologia legal.

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