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QUALITY & RESEARCH

True Progress in Orthobiologics Requires That We Police Ourselves and Each Other

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▶ The orthobiologic product segment now represents 10 percent of the worldwide orthopaedic marketplace, with 2019 sales exceeding $5 billion worldwide. Although bone grafting and viscosupplementation products bear the lion's share of that revenue figure, new products are introduced every month. There are superb examples of sponsor companies investing the substantial sums of money necessary to demonstrate the safety and efficacy required for Food and Drug Administration (FDA) clearance or approval. Sadly, however, there are far too many other cases where companies have improperly side-stepped the FDA, misguided clinicians, and defrauded not only the surgeon community but also the general public and other federal agencies as well.

Fortunately, AAOS is now dedicating more resources and focus to the topic of biologic product development and responsible clinical use. Formation of the Committee on Devices, Biologics, and Technology will shine a brighter light on the need for evidence-based content and assist in developing educational programs, regulatory resources, and symposia. As the use of biologic products expands beyond the purview of orthopaedic surgeons and into the realm of pain management, podiatry, and physical medicine and rehabilitation specialties, it is even more important that clinicians, educators, and related professional societies understand and manage this product category.

The product category manifesting the greatest level of misunderstanding among physicians is that of human cells, tissues, and cellular and tissue-based products (HCT/Ps). As a result of the simultaneously complex and subtle distinctions within this FDA class of products, many physicians have misunderstood the Code of Federal Regulations that govern the approval and clinical use of HCT/Ps. For this reason, in part, the FDA issued a series of updated Guidance Documents in 2017 that established a clear roadmap regarding what is considered a biologic, device, drug, combination product, or HCT/P that is exempt from the otherwise rigorous approval requirements of the aforementioned classifications—such products are referred to as "Section 361 Exempt." To facilitate the smooth adoption of the refined guidelines, the FDA issued a policy calling for a discretionary enforcement period of three years, through November, allowing a grace period to companies that are not in compliance to meet with the FDA and move toward formal approval. Just recently, as a result of the impact of COVID-19 on industry efforts, the original deadline has been extended to June 2021.

Since 2017, however, there has been an explosion of companies offering myriad products they claim to be "361 exempt" but have no legitimate basis for that qualification. Furthermore, many of the firms have made no effort to engage the FDA in a proper development path toward regulatory approval. The most egregious offenders are akin to the "snake oil" salesman of the 1800s but are today hawking HCT/Ps they claim are effective mesenchymal stem cells, exosomes, stromal vascular fraction (SVF), micronized amnion, and more. To be clear, these products are *not* eligible for Section 361 exemption, and the FDA has not approved *any* mesenchymal stem cell, exosome, SVF, or micronized amnion product for *any* indication. Those HCT/Ps are considered adulterated and illegal products.

Unfortunately, in the race to capitalize on patient-driven interest in

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PRACTICE MANAGEMENT

The Devil Is in the Details

Evaluation and management 2.0

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EDITOR'S NOTE: AAOS partners with KarenZupko & Associates, Inc. (KZA), on the organization's coding education, and KZA often provides content for *AAOS Now*. For more information, visit www.aaos.org/membership/coding-and-reimbursement.

▶ Beginning Jan. 1, 2021, the level of service selection for new and established patient "office or other outpatient" visits will be based only on either medical decision-making (MDM) or time. Current Procedural Terminology (CPT) is making dramatic changes to the way those services are defined and documented, impacting billions of healthcare dollars.

Time and MDM have been reconfigured in the updated 2021 guidelines to make the "documentation clinically relevant and reduce the excessive burden" associated with duplicate services. Below is a list of 10 important things you need to know about the biggest change in evaluation and management (E/M) services by CPT in decades:

1. The updated CPT E/M guidelines

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so-called "stem cells"; biologic therapies; and "regeneration" of a more vital, healthy, and functional body, many new suppliers have brought new products to market that lack scientific controls, validity, and meaningful evidence. The opportunistic avarice of companies and physicians in response to patient demand has led to mercenary behavior that has begun to sully the orthopaedic field's reputation. Do not be fooled by the overzealous sales representative who comes to your office making false claims. The *only* acceptable use of these products is in the context of an FDA-registered clinical trial as part of an approval process; even then, such HCT/Ps may not be sold to a physician, hospital, or patient.

There is another group of sponsor companies that make inappropriate and illegal claims regarding devices that have been properly cleared for the simple preparation of platelet-rich plasma (PRP), bone marrow aspirate concentrate (BMAC), or adipose tissue.

In such cases, the device used to prepare the HCT/Ps may be legally available, but if marketed and promoted in a manner that is incorrect or misleading, there can be severe consequences for the sponsor company and physician user. For example, neither PRP nor BMAC has any FDA-approved indication language that allows promoting or marketing in the treatment of any pathology, including osteoarthritis, epicondylitis, and spine fusion.

In terms of how we as clinicians govern ourselves, it is fundamental to recall that our AAOS Code of Professional Ethics, as well as laws from the Federal Trade Commission (FTC), require that when we market and promote our clinical practice through any medium, we must not do so in a misleading, untruthful, or deceptive manner.

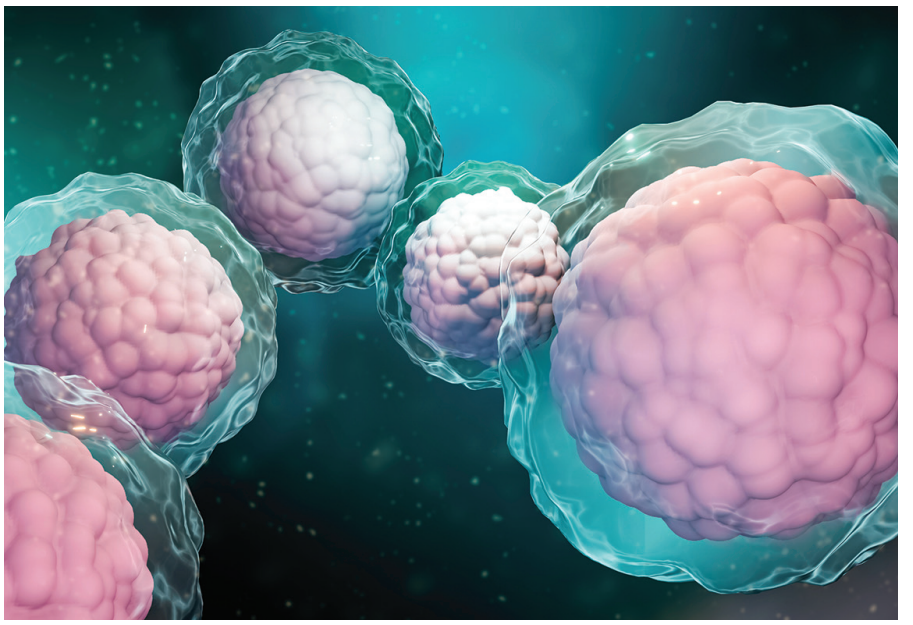
Ignorance of the law or use of unsubstantiated evidence is not a legitimate defense. It is our responsibility to demand rigorous clinical and scientific evidence from sales representatives, as well as unambiguous, nonconfidential correspondence from the FDA indicating the regulatory status of the product in question. If those materials are not convincing, or made available at all, the product probably is not in compliance with FDA or FTC regulations. Using and/or promoting such products in a noncompliant manner can carry significant risks to your practice, reputation, livelihood, and, most importantly, patients.

What does one do to remain compliant with FDA, FTC, and other state medical board regulations? First, take responsibility to educate yourself on the "rules of the road," and engage others to assist you in understanding the rules if necessary. As previously noted, the FDA Guidance Documents are both complex and subtle. With that said, by following a few simple precepts, you can avoid some of the major pitfalls that put careers at risk. The following suggestions relate to any form of marketing or promotion, whether in print, on your website, or over the airwaves:

- Never claim that you are using stem cells to treat any musculoskeletal condition, period. Doing so tells the authorities that you are directly violating federal law.
- Never claim that you are able to regenerate articular cartilage by the injection of any biologic agent. There are no products approved with that indication.
- Never claim that you are regenerating intervertebral disk tissue by the injection of any biologic agent. As noted previously, no products are approved for that indication yet either.
- Any claims used for procedure or product promotion must be substantiated with "objective, valid, scientific data," or you may face false-advertising charges from the FTC, which can bring sizeable fines and significant reputational damage.
- All patient testimonials are regarded as "clinical claims" and must reflect FDA-approved labeling. Even if your treatment was legally an off-label use of a cleared or approved product, testimonials are limited to on-label indications and claims.

Some surgeons who read these suggestions may regard them as too conservative "because everyone else is already saying these things." The answer to that lies in an analogy of highway driving. Many people on the interstate travel well above the posted speed limit, and as more cars speed along at 80 mph, the police seem less likely to pull over a speeder. To be sure, they cannot pull everyone over and issue citations; however, they *will* pull someone over and make an example of them so all passing cars see and slow down. Similarly, the FDA and FTC do not have enough resources to identify and sanction all "bad actors." However, they can make examples of physicians by imposing injunctions and multimillion-dollar fines on those who inappropriately use stem cells and/or make improper claims. By doing so, they hope to grab the attention of other physicians who are not acting in a compliant manner.

The question we should all be asking ourselves, as well as our peers in other departments or at hospitals across town, is whether the professional, personal, and clinical consequences of noncompliance are worth the risks of behaving badly in order to make a few extra dollars.



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AAOS' focus on biologics

With the creation of the Committee on Devices, Biologics, and Technology (DBT), AAOS is forging ahead with its strategic investment in orthobiologics. Over the next five years, AAOS will prioritize research and development for a biologics-focused competency within the Academy's existing business through a series of initiatives that includes:

- educational content (website, white papers)
- symposia and evidence-based systematic reviews
- high-quality evidence/technology reviews
- investigator grants
- advocacy

The DBT Committee has also discussed the importance of building relationships with other medical specialty societies, with the shared sentiment that a unified voice can speak louder than the sum of its parts, especially when it comes to education, messaging, and advocacy. The committee plans to explore opportunities for unified collaboration between relevant specialty organizations under the Biologics Alliance™ moniker.

For more information on AAOS' biologics programming, visit www.aaos.org/biologics. For more information about the DBT Committee or to express your interest in learning more about and/or participating in AAOS' efforts in this area of study, email biologics@aaos.org.

A reference for the data cited can be found in the online version of this article, available at www.aaosnow.org.

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