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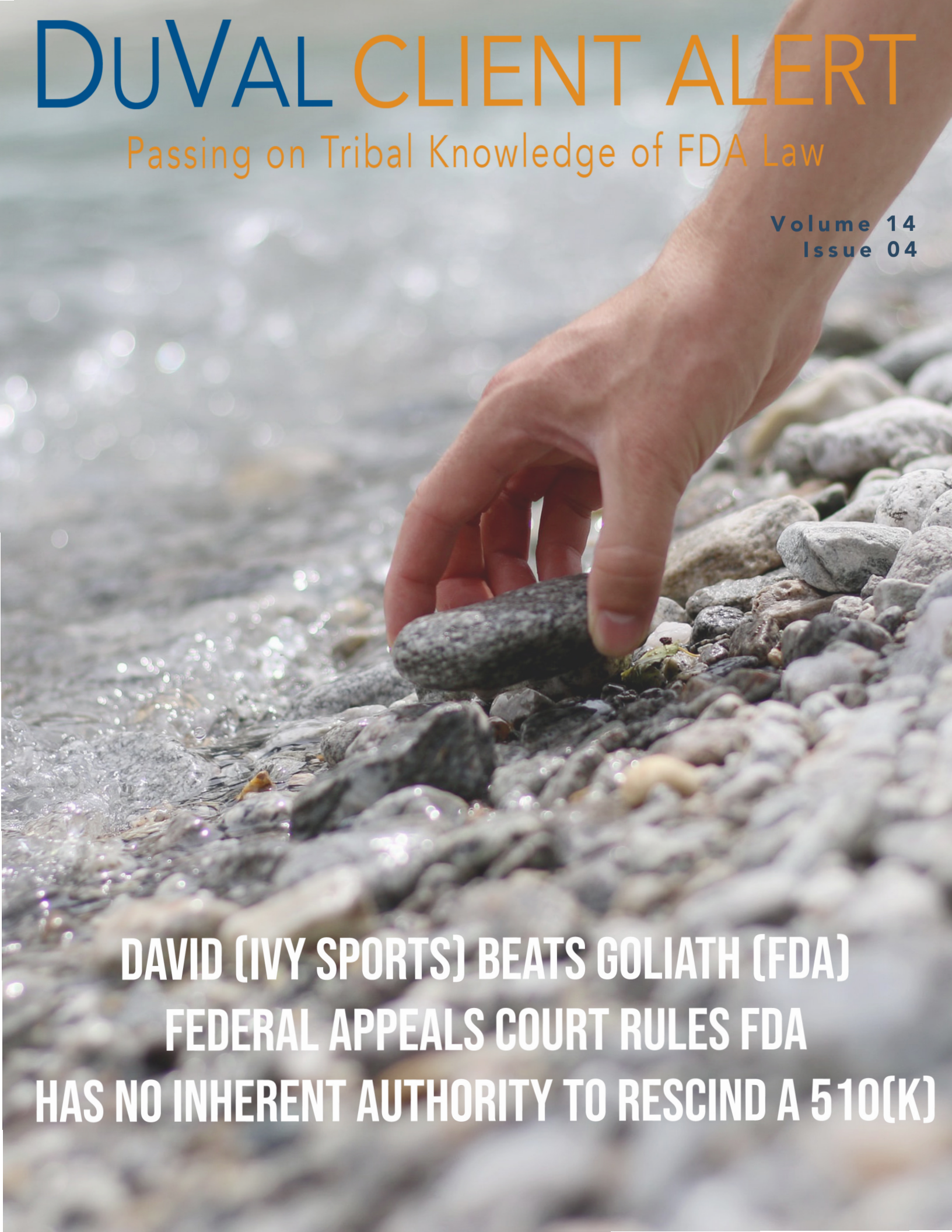

DAVID (IVY SPORTS) BEATS GOLIATH (FDA)
FEDERAL APPEALS COURT RULES FDA HAS NO INHERENT AUTHORITY TO RESCIND A 510(K)

David (Ivy Sports) Beats Goliath (FDA)—Federal Appeals Court Rules FDA has No Inherent Authority to Rescind a 510(k)

INTRODUCTION

FDA again misjudged its strength and position and the little principled warrior, Ivy Sports Medicine, LLC, whose predecessor was ReGen Biologics. In this epic battle Ivy Sports is a small company and seemingly ill-equipped to do battle with the giant, FDA. But Ivy Sports stood up to FDA and knocked it down and out by winning a landmark case in the Federal Circuit Court of Appeals for the District of Columbia. We all remember the ReGen case in which FDA (more directly, Center Director Dr. Shuren) relentlessly pursued the 510(k) clearance obtained by the company from FDA in 2008. The company's successor Ivy Sports Medicine, LLC filed a lawsuit to challenge FDA's attempted rescission of the 510(k) and the court issued its decision on Friday, September 26, 2014. ***The court's decision in the Ivy Sports Medicine case is a solid rebuke of the Center for Devices and Radiological Health (CDRH) which tried to create for itself a "right to rescind" a 510(k) out of whole-cloth, where no such statutory right had been given to FDA by Congress***. It was a right FDA has repeatedly sought from Congress through legislation in the past and has never received. So FDA decided on its own initiative it would invent this right for itself from its own interpretation of its delegated administrative authority—a common theme with this FDA Administration for sure. The court disagreed with FDA. It reined in FDA's liberal and generous interpretation of its own authority. It

is also vindicated the good folks from ReGen Biologics and its successor Ivy Sports Medicine, who designed and obtained a 510(k) for an absorbable surgical mesh called the Collagen Scaffold which has utility in knee-replacement surgeries, only to have FDA attempt to take away that clearance through this CDRH-created "inherent rescission authority."

FDA's Argument For "Inherent Reconsideration Authority" to Rescind a 510(k)

In the case the FDA argued that it has "inherent reconsideration authority" to rescind a 510(k) when it believes it has made a mistake in clearing the device. FDA in the case seemed to use the term inherent ***reconsideration*** authority to disguise and make more acceptable, the less palatable term inherent ***rescission*** authority—probably because FDA has been unsuccessful getting such power from Congress. Industry's concern is that granting FDA that unfettered right to rescind a 510(k) would allow FDA to reconsider any number of 510(k) devices on the market today. For industry, the *Ivy Sports* court's decision provides a ray of hope that FDA cannot make-up-rules-as-they-go-along to achieve a result that a new FDA Administration (Dr. Shuren's), revisiting what a previous FDA Administration (Dr. Schultz's) had done just because the new administration has a differing scientific and regulatory opinion (and possibly another political agenda).

The *Ivy Sports* court concluded that FDA did not exercise its clear statutory authority to use the reclassification process under Section 360c(e) of the Food, Drug and Cosmetic Act (the "Act") to rescind the 510(k) through notice and comment reclassification rulemaking. The court stated FDA "short-circuited the statutory reclassification process" by relying on its "inherent reconsideration authority." The *Ivy* Sports court concludes the Act does not contain an express provision granting FDA authority to reconsider its substantial equivalence determinations. The court in *Ivy Sports* stated as follows:

…it would be unreasonable under this statutory scheme to infer that FDA retains inherent authority to short-circuit or end-run the carefully prescribed statutory reclassification process in order to correct the same mistake. Indeed, accepting FDA's assertion of inherent authority would render Section 360(c) a dead letter in many cases because FDA could often reclassify a device without complying with the procedural requirements of that provision, in particular notice and comment.

The irony of the majority and the dissenting opinions in the *Ivy Sports* case is that neither of them seems to be aware of the fact that FDA has continually asked Congress to grant it rescission authority by statute. If FDA truly does have inherent authority to rescind, it would not need to request legislation for express authority to rescind. To request that authority from Congress is to presume it is because FDA does not believe it has that authority. Importantly, Congress has refused to give FDA that authority, presumably out of concern it would be misused by the Agency (certainly that is the argument and fear of industry).

Case/Product History

This case has a long and convoluted history. In December 2008, ReGen obtained FDA clearance to market its device. The product had languished at FDA for years and eventually the company brought political pressure to bear on the Agency in the form of Congressmen and U.S. Senators making calls to and writing the Commissioner and CDRH Center Director, Dr. Dan Schultz. The product was eventually cleared and a special medical device panel agreed with FDA (the Dr. Schultz Administration) that the device was safe and effective. The device received the long sought-after clearance. The celebration over ReGens' clearance was truncated by press reports alleging that political pressure had skewed FDA's review process.

When the Obama Administration came into office the newly appointed Acting Commissioner ordered an internal investigation of the Collagen

Scaffold's review process. Dr. Shuren and others eventually authored an internal FDA report which identified "multiple departures from processes, procedures, and practices" that raised "serious questions about whether the integrity (as well as the quality) of the review process was compromised." After the report was issued and when he became Center Director, Dr. Shuren (Dr. Schultz's successor) recommended reevaluation of Dr. Schultz's decision to clear the ReGen device.

Dr. Shuren then convened a second panel of medical and scientific experts to review the ReGen device. They concluded the device was indeed safe with some concerns with efficacy. They did not recommend the device be pulled from the market. But Dr. Shuren did. He recommended the clearance for the device be rescinded despite questionable authority to do so stating the clearance "was in error" and that to "rectify the error" FDA would rescind the substantial equivalence determination. FDA issued an order requiring ReGen to immediately pull the scaffold from the market.

As part of its findings the court also found there was no misconduct that would allow for a reconsideration of the 510(k). The court even affirmed the right of a company to enlist the assistance of their elected representatives. The court stated:

> For example, FDA's report on the scaffold's review process acknowledged that communications between members of the New Jersey congressional delegation and FDA officials were "not inappropriate." J.A. 850. And in fact, representing the interests of constituents is a key and proper part of the job of Representatives and Senators. Indeed, FDA received pressure from other Members of Congress to *change* the original reclassification decision. Not surprisingly, therefore, Members of Congress were on both sides of the question. The Member' expression of their views—on both sides—was not misconduct for purposes of the *American Methyl* exception.

ReGen filed for bankruptcy and filed suit against the Agency losing in Federal District Court. ReGen, and its successor Ivy Sports Medicine, argued FDA had no authority to rescind a 510(k) except through the reclassification process under Section 360c(e) of the Food, Drug and Cosmetic Act (the "Act"). The District Court granted FDA's motion for summary judgment and Ivy Sports appealed. The Federal Circuit Court of Appeals for the District of Columbia overturned the District court in this case and directed the District Court to vacate FDA's decision and to remand the case back the Agency for further proceedings.

The Impact of This Case Upon Industry

The impact of this case cannot be underestimated on a number of levels. ***First, FDA not infrequently exceeds its statutory and regulatory authority often granting to itself powers and interpretations of law and regulations well outside the scope of that actually given to them.*** FDA has had its interpretations of law and regulations checked by such representative and famous cases as the *Washington Legal Foundation* case, the *IMS Health* case and the *Caronia* case, all 1st Amendment cases. It also lost the *Utah Medical* case as it relate to its authority to dictate specific CGMP/QSR requirements to a medical device manufacturer. In the *Prevor* case the court did not agree with FDA's interpretation of how to determine the definition of "primary mode of action" of a combination product. And now we have the Ivy Sports/ReGen case.

These cases all stand for the proposition that FDA is not always right in its interpretations, which can often be self-serving and extend authority to areas and plateaus not granted to them by Congress.

Our firm routinely takes appeals to FDA in which upper management overturns reviewers and branch management on the interpretation of regulations and guidance. These appeals reveal there can be legitimate differences of opinion, even within the Agency. We have most recently seen this happen in FDA's treatment of "stage-gated" reviews in which FDA

makes an upfront legal/regulatory definitional interpretation that a 510(k) device does not: 1) have the same intended use, 2) same technological characteristics, and/or raises different questions of safety and effectiveness, without ever looking at an applicant's data and earning its user fees. This avoidance of looking at the data submitted is inappropriate under the statute and regulations, yet the Agency maintains its right to do so. Click here for our Client Alert on stage-gated reviews.

We have also recently seen FDA attempt to change the 510(k) standard of "substantial equivalence" by proposing the following guidance, "*Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Pre-Market Notifications [510(k)] With Different Technological Characteristics*," July 15, 2014 Docket No. FDA-2014-D-0900 (the "Benefit-Risk Guidance"). Benefit–risk determinations have no place in the 510(k) program, because the benefit of the underlying predicate device is presumed (in the clearance of the predicate) and all the 510(k) applicant needs to show is that its device is substantially equivalent to its chosen predicate(s). To restate this, the underlying benefit-risk of any device has already been accepted in the decision to clear the predicate device. There is no need to make a benefit-risk determination in a 510(k), yet FDA has created it out of whole-cloth. The 510(k) program has statutorily-defined criteria (quoted above) which FDA ignores in this proposed guidance, creating the program FDA wants, not what Congress created. The Benefit-Risk Guidance document, if adopted as final, will continue to erode, redefine and emasculate Congress' original intent for the 510(k) program. This is yet another example of FDA over-stepping its bounds and creating new and different authority for itself. Click here for our submission to the FDA Docket challenging FDA's proposed guidance on benefit-risk factors in 510(k) submissions.

All of this is to say, we must continually keep the natural evolution of any bureaucracy in check because it will continually expand interpretations to grow its jurisdiction and authority and make the regulatory framework more complex and need more people to administer it. We often wonder if it is regulatory fiefdom-building or regulatory boredom, or both, that drives this

need to create more, increasingly-complex rules. This in a great sense is what we fight when we fight these individual battles with FDA, or any federal bureaucracy for that matter.

Second, hopefully this decision will make the Agency pause and realize that the world outside of FDA's enclave does not always agree with FDA's take on its authority and FDA will rein in its thinking—but don't count on it. An idealist would hope FDA will become more circumspect about how sure they are of their interpretations of the scope and content of their authority. When FDA takes more authority than that to which it is entitled, industries' only recourse is to challenge them through an internal appeal where FDA plays the role of prosecutor, judge and jury and the desk is stacked against industry. FDA mostly agrees with itself and typically upholds the decisions of its rank and file. Or industry can challenge FDA in court which is commercially far too time-consuming and expensive to be a practical choice. By the time a court resolves a dispute in can be 3 to 6 years later (take the ReGen/Ivy Sports case as an example). For that reason companies often take a more practical, yet painful, decision to roll over and acquiesce to the Agency's (often incorrect or stretched) position.

Third, may be this is a clarion call for industry to request that Congress restrict the Agency's continued proliferation of guidance documents and return to old-fashioned, more thoughtful and deliberative rulemaking. At a minimum, we need to bolster the manner in which guidance documents are proposed and finalized. Otherwise industry simply falls victim to an agenda-driven agency that is drunk on its own perceived power. The court in Ivy was very concerned that FDA was short-circuiting or doing an end-run around notice and comment procedures. The court stated:

> *FDA obviously thinks notice and comment is unnecessary here, a not uncommon sentiment among agencies that want to take action more promptly.* But notice and comment helps to prevent mistakes, because agencies receive more input and

> information before they make a final decision. ***And notice and comment also helps ensure that regulated parties receive fair treatment, a value basic to American administrative law.*** So notice and comment, while somewhat burdensome, serves important purposes both generally and in this statute.

Industry has long ceded to FDA too much power through the allowance of guidance documents issued under Good Guidance Practices. Guidance documents were good at a time when industry wanted FDA's thinking about its interpretation of statutes and regulations. Guidance documents can be issued far more quickly than regulations through notice and comment rulemaking. The problem is that FDA has gotten lazy and simply puts out guidance, often with little to no meaningful input from industry, and industry has not challenged them. Keeping up with the proliferation of FDA guidance documents is like drinking out of a fire hose. We are all drowning. And the quality of water (guidance documents) is not always high because it most often has not had the benefit of meaningful, if any, industry input.

More importantly, FDA has a misplaced sense of prerogative and authority in that it uses guidance documents to create more authority, or more expansive authority, than it has actually been given by Congress. FDA waives the banner of patient safety in all it does, and as a result it frequently has misplaced public opinion on its side. Industry needs Congress' help to rein in FDA.

CONCLUSION

We are excited by the court's decision in the *Ivy Sports* case. It was a correct decision. We've been saying FDA does not have rescission authority publicly for years. Our hope is that this *Ivy Sports* case will make industry and Congress revisit the giant we've created, called FDA, because like Goliath it's clearly big, imposing and threatening to the existence of the device industry, especially the small companies who try to stand up to it. Fortunately, we have a judiciary like the *Ivy Sports* court to keep them in

check, because FDA does not police itself well and Congress often does not do its job in reviewing FDA's jurisdictional-creep.

DuVal & Associates
Drug, Device and Food Law

DuVal & Associates is a boutique law firm located in Minneapolis, Minnesota that specializes in FDA regulations for products at all stages of the product life cycle. Our clientele includes companies that market and manufacture medical devices, pharmaceuticals, biologics, nutritional supplements and foods. Our clients range in size from Global Fortune 500 companies to small start-ups. As one of the only dedicated FDA regulatory law firms in the United States, our mission and absolute focus is providing our clients appropriately aggressive, yet compliant, guidance on any FDA related matter. We pride ourselves not only on our collective legal and business acumen, but also on being responsive to our client's needs and efficient with their resources. DuVal & Associates understands the corporate interaction between departments like regulatory affairs, marketing, sales, legal, quality, and clinical, etc. As former industry managers in the drug and device spaces, we have been in your shoes. Our firm has extensive experience with government bodies. We understand what it takes to develop and commercialize a product and bring it successfully to the market and manage its life cycle. Impractical or bad advice can result in delays or not allow for optimal results; while practical, timely advice can help companies succeed.

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