United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued April 8, 2014 Decided September 26, 2014

No. 13-5139

IVY SPORTS MEDICINE, LLC,
APPELLANT

v.

SYLVIA MATHEWS BURWELL, SECRETARY OF HEALTH AND HUMAN SERVICES (IN HER OFFICIAL CAPACITY), ET AL.,
APPELLEES

Appeal from the United States District Court
for the District of Columbia
(No. 1:11-cv-01006)

Matthew M. Hoffman argued the cause for appellant. With him on the briefs was *Mark A. Heller*.

Adam C. Jed, Attorney, U.S. Department of Justice, argued the cause for appellees. With him on the brief were *Stuart F. Delery*, Assistant Attorney General, *Ronald C. Machen, Jr.*, U.S. Attorney, and *Scott R. McIntosh*, Attorney.

Before: GRIFFITH, KAVANAUGH, and PILLARD, *Circuit Judges*.

Opinion for the Court filed by *Circuit Judge* KAVANAUGH, with whom *Circuit Judge* GRIFFITH joins.

Dissenting opinion filed by *Circuit Judge* PILLARD.

KAVANAUGH, *Circuit Judge*: This case concerns the Food and Drug Administration's regulation – and subsequent re-regulation – of a medical device called the Collagen Scaffold, an absorbable surgical mesh that is designed for use in knee-replacement surgeries. In December 2008, the manufacturer of the scaffold, ReGen Biologics, obtained FDA clearance to market the device. FDA's clearance of the scaffold soon came under fire in the press and from some Members of Congress amid allegations that the process had been tainted by improper political pressure from *other* Members of Congress. An internal FDA investigation concluded that some procedural irregularities had occurred during the agency's review of the device.

Following the internal investigation, FDA did not exercise its clear statutory authority to reclassify the device. Reclassification would force the device off the market and require the device to undergo the extensive pre-market approval process before it could again be marketed. That statutory reclassification process generally requires FDA to provide notice and an opportunity for comment before the agency reclassifies a device. FDA here did not give notice and opportunity for comment. Rather, FDA short-circuited the statutory reclassification process by relying on what it called its inherent reconsideration authority. Asserting that inherent authority, FDA reevaluated the scaffold and concluded that the agency had erred in allowing the device to be sold. FDA issued an order rescinding its clearance decision, forcing ReGen to immediately pull the scaffold from the market. ReGen subsequently filed for bankruptcy.

ReGen and its successor in interest, Ivy Sports Medicine, challenged FDA's decision to rescind the clearance

determination as procedurally flawed. The District Court granted summary judgment to FDA, and Ivy now appeals. Because we conclude that FDA did not follow the proper statutory procedure for reclassifying a device, we reverse the judgment of the District Court. We direct the District Court to vacate FDA's decision and to remand to the agency for further proceedings.

I

A

In 1976, Congress amended the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, to grant FDA authority to regulate medical devices intended for human use. Devices fall into one of three categories – Class I, Class II, or Class III. A device's classification is determined based on "the degree of regulation thought necessary to provide reasonable assurance of each device's 'safety and effectiveness.'" *Contact Lens Manufacturers Association v. FDA*, 766 F.2d 592, 594 (D.C. Cir. 1985).

The classification of a device matters because the three classes trigger different approval processes. In order to enter the market, manufacturers of Class III devices first must go through the "premarket approval" process. "That process generally requires extensive clinical research on a new device to ensure the device's safety, and it often takes significant time." *Cytori Therapeutics, Inc. v. FDA*, 715 F.3d 922, 923 (D.C. Cir. 2013). Class I and II devices are considered to pose fewer risks and are therefore able to enter the market more easily. Rather than requiring pre-market approval, Class I and II devices are subject either to "general controls" such as labeling restrictions (for Class I devices), or a combination of general controls and "special controls," such as

performance standards (for Class II devices). *See* 21 U.S.C. § 360c(a)(1)(A)(i), (a)(1)(B).

How does a device initially get classified into Class I, II, or III? The Act makes Class III the default category for new (that is, post-1976) medical devices, unless and until FDA finds that one of two conditions has been met. *See id.* § 360c(f)(1). First, FDA may determine that a device is "substantially equivalent" to a pre-existing Class I or II device. *Id.* § 360c(f)(1)(A)(ii). To be substantially equivalent to a pre-existing Class I or II device, the new device must have "the same intended use as the predicate device," and either (i) have "the same technological characteristics as the predicate device" or (ii) be shown to be as safe and effective as the predicate device. *Id.* § 360c(i)(1)(A). Second, regardless of whether a device is substantially equivalent to an existing device, FDA may make a de novo determination that a device meets the statutory definitions of Class I or II. *See id.* § 360c(f)(1)(B), (f)(2)-(3). That determination may be made on FDA's own initiative or in response to the device manufacturer's petition for de novo classification.

Here is how it works in practice: Classification of a new medical device into Class I or II is usually obtained by submitting to FDA a "premarket notification," which in turn triggers the FDA's substantial equivalence review. *See id.* § 360(k). In the pre-market notification, the manufacturer states the new device's intended use, identifies the predicate devices to which the new device is substantially equivalent, and offers a proposed classification. *See id.*; 21 C.F.R. § 807.87. If FDA agrees that the new device is substantially equivalent to an existing Class I or Class II device, it issues a classification order allowing the device to be marketed subject to appropriate restrictions. *See* 21 C.F.R. § 807.100. But if FDA disagrees with the proposed classification, the device

remains in Class III and must go through the pre-market approval process, unless FDA subsequently approves a petition for de novo classification. *See* 21 U.S.C. § 360c(f)(3)(A).

After a device has been initially classified, there is also a process for FDA reclassification. The Act includes a provision, Section 360c(e), allowing FDA to change the classification given to a device. *See* 21 U.S.C. § 360c(e). During the time period relevant to this litigation, that provision stated: "Based on new information respecting a device, the Secretary may, upon his own initiative or upon petition of an interested person, by regulation (A) change such device's classification, and (B) revoke, because of the change in classification, any regulation or requirement in effect . . . with respect to such device." *Id.* § 360c(e)(1) (2011). Because reclassification must be done "by regulation," it must be done in accord with certain procedural requirements, including notice and comment. *See* FDA Br. 36; 21 U.S.C. § 360c(e); 21 C.F.R. § 860.130(c).

B

ReGen Biologics, Inc. was a New Jersey-based medical device manufacturer. In 1993, ReGen began research on a new device for use in certain knee-repair surgeries. The fruit of that labor, called the Collagen Scaffold, is a crescent-shaped surgical mesh made of bovine collagen. According to ReGen, the Collagen Scaffold was intended to reinforce and repair the knee cartilage remaining after knee surgery and to provide a scaffold on which new tissue could grow.

In 2004, ReGen submitted a Class III premarket approval application but subsequently withdrew it and sought to proceed through the quicker premarket notification process for Class I or Class II devices. In 2005, ReGen submitted to

FDA its first pre-market notification for the Collagen Scaffold. Shortly thereafter, FDA issued a letter finding that the scaffold was not substantially equivalent to its claimed predicates. FDA eventually agreed to convert that finding into a request for additional information. After receiving the requested information, FDA again determined that the scaffold was not substantially equivalent.

In late 2006, ReGen submitted a second pre-market notification with revised labeling. Following more back-and-forth between ReGen and FDA, the agency issued another finding that the Collagen Scaffold was not substantially equivalent to existing devices. A few months after this second decision, four members of New Jersey's congressional delegation wrote to the FDA Commissioner expressing concern about FDA's process for reviewing the scaffold. Representatives from ReGen later met with the Commissioner and with Dr. Daniel Schultz, the director of FDA's Center for Devices and Radiological Health, the office that oversees device approval decisions. Although the FDA officials declined to take further action on the denied application, Dr. Schultz advised ReGen that it could submit a new pre-market notification with additional revisions.

ReGen took Dr. Schultz up on his suggestion and submitted a third pre-market notification in July 2008. As they had before, FDA's staff reviewers recommended that the scaffold be found not substantially equivalent to the claimed predicates. Rather than issue a final decision, however, Dr. Schultz decided to convene and seek input from an expert advisory panel. That panel ultimately concluded that the scaffold "was as safe and effective as the predicate devices." FOOD & DRUG ADMINISTRATION, ORTHOPAEDIC AND REHABILITATION DEVICES PANEL MEETING – NOVEMBER 14, 2008 (SUMMARY). Based on the panel's conclusions and

other information in the administrative record, Dr. Schultz issued a letter finding that ReGen had demonstrated substantial equivalence and classifying the Collagen Scaffold into Class II.

ReGen's victory would prove short-lived. A few months after ReGen received clearance to market the Collagen Scaffold, the *Wall Street Journal* published an article alleging that political pressure had skewed FDA's review process. *See* Alicia Mundy, *Political Lobbying Drove FDA Process*, WALL ST. J., Mar. 6, 2009, at A1. The same day that the *Wall Street Journal* article appeared, a United States Senator contacted FDA to raise concerns that ReGen had been allowed to play an outsized and inappropriate role in the process. Other Members of Congress later raised similar concerns. And in April 2009, at the same time ReGen was preparing for its first commercial distributions of the scaffold in the United States, a group of FDA employees wrote a letter to President Obama accusing Dr. Schultz and the FDA Commissioner of improperly influencing the results of the agency's review.

Faced with those and other allegations of impropriety, FDA's newly appointed Acting Commissioner ordered an internal investigation of the Collagen Scaffold's review process. The investigation culminated in a report issued in September 2009. *See* FOOD & DRUG ADMINISTRATION, REVIEW OF THE REGEN MENAFLEX: DEPARTURES FROM PROCESSES, PROCEDURES, AND PRACTICES LEAVE THE BASIS FOR A REVIEW DECISION IN QUESTION, PRELIMINARY REPORT (2009). The report 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." *Id.* at 1, 22. Among other things, the report criticized ReGen's access to high-level FDA officials, and those officials' involvement in

the decisionmaking process; communications between Members of Congress and the FDA Commissioner; and ReGen's level of involvement in the expert panel proceedings. Although the report stopped short of concluding that the review process had been compromised, it recommended reevaluation of Dr. Schultz's decision to clear the Collagen Scaffold. *Id.* at 23.

Following the report's publication, FDA appointed a new team to review the Collagen Scaffold. That team concluded that the device was not substantially equivalent to its claimed predicates. Dr. Jeffrey Shuren, who had succeeded Dr. Schultz as head of FDA's Center for Devices and Radiological Health, then convened a second expert panel. The second panel's findings were mixed; although the scaffold was "generally considered safe," the panel members raised "some concerns about efficacy." J.A. 1020. In October 2010, Dr. Shuren notified ReGen that the clearance of the scaffold "was in error," and that to "rectify this error" FDA would rescind its substantial equivalence determination. Letter from Dr. Jeffrey Shuren, Director, Center for Devices and Radiological Health, to Dr. Gerald E. Bisbee, Jr., Chairman and Chief Executive Officer, ReGen Biologics, Inc. (Oct. 14, 2010). That decision, in turn, meant that the Collagen Scaffold would be in Class III and have to go through the extensive pre-market approval process to be marketed again. An official rescission order followed in March 2011, forcing ReGen to withdraw the Collagen Scaffold from the market.

ReGen then filed this suit in the District Court seeking review of FDA's decision pursuant to the Administrative Procedure Act. *See* 5 U.S.C. § 702. During the pendency of the case, ReGen went bankrupt and Ivy Sports Medicine, LLC

became the successor in interest to ReGen and was substituted as plaintiff.

Before the District Court, Ivy argued that FDA's rescission order was unlawful. Of relevance here, Ivy asserted that FDA did not have inherent authority to rescind its substantial equivalence determination; rather, according to Ivy, FDA should have exercised its statutory reclassification authority if it wanted to change the original classification decision. The District Court disagreed and granted summary judgment to FDA. Our review of the District Court's decision is de novo. *See Virginia Department of Medical Assistance Services v. HHS*, 678 F.3d 918, 921 (D.C. Cir. 2012).

II

FDA asserts that it had "inherent authority" to rescind its determination that the Collagen Scaffold was substantially equivalent to devices already in the market. Rescinding that determination had the effect of putting the device into Class III, and thus required completion of the extensive pre-market approval process before the scaffold could be marketed again. FDA used its inherent authority to rescind rather than its statutory reclassification authority. As a result, FDA did not go through the procedures – including notice and comment – that are required for reclassification.

The Act does not contain an express provision granting FDA authority to reconsider its substantial equivalence determinations. But as FDA notes, administrative agencies are assumed to possess at least some inherent authority to revisit their prior decisions, at least if done in a timely fashion. *See, e.g., American Methyl Corp. v. EPA*, 749 F.2d 826, 835 (D.C. Cir. 1984) ("We have held that agencies have an inherent power to correct their mistakes by reconsidering their decisions within the period available for taking an

appeal."); *Mazaleski v. Treusdell*, 562 F.2d 701, 720 (D.C. Cir. 1977) ("We have many times held that an agency has the inherent power to reconsider and change a decision if it does so within a reasonable period of time.") (quoting *Gratehouse v. United States*, 512 F.2d 1104, 1109 (Ct. Cl. 1975)); *Albertson v. FCC*, 182 F.2d 397, 399 (D.C. Cir. 1950) ("in the absence of any specific limitation," reconsideration available "within the period for taking an appeal"); *see generally* Daniel Bress, Note, *Administrative Reconsideration*, 91 VA. L. REV. 1737 (2005). As this Court explained in an oft-repeated framing of the principle, inherent authority for timely administrative reconsideration is premised on the notion that the "power to reconsider is inherent in the power to decide." *Albertson*, 182 F.2d at 399.

But we have also recognized that any inherent reconsideration authority does not apply in cases where Congress has spoken. In *American Methyl Corp. v. EPA*, 749 F.2d 826 (D.C. Cir. 1984), we held that an agency may not rely on inherent reconsideration authority "when Congress has provided a mechanism capable of rectifying mistaken actions." 749 F.2d at 835. In such circumstances, we concluded, "it is not reasonable to infer authority to reconsider agency action." *Id.*; *see also New Jersey v. EPA*, 517 F.3d 574, 583 (D.C. Cir. 2008) ("Congress . . . undoubtedly can limit an agency's discretion to reverse itself"). Put more simply, our cases assume that Congress intends to displace an administrative agency's inherent reconsideration authority when it provides statutory authority to rectify the agency's mistakes.

Ivy argues that this case falls squarely within the ambit of cases like *American Methyl*. In particular, Ivy contends that Congress precluded FDA from exercising inherent authority to rescind substantial equivalence determinations by creating

in 21 U.S.C. § 360c(e) a specific statutory mechanism to correct alleged device classification errors. As relevant here, that provision states: "Based on new information respecting a device, the Secretary may, upon his own initiative or upon petition of an interested person, by regulation (A) change such device's classification, and (B) revoke, because of the change in classification, any regulation or requirement in effect under section 360d or 360e of this title with respect to such device." 21 U.S.C. § 360c(e)(1) (2011). To do so, the agency must first give notice and opportunity for comment. *See* FDA Br. 36; 21 U.S.C. § 360c(e); 21 C.F.R. § 860.130(c).

For its part, FDA acknowledges that it could have used the statutory reclassification procedure in Section 360c(e) to reclassify the Collagen Scaffold into Class III and thereby remove it from the market. *See* FDA Br. 39. But FDA argues that nothing in the Act or the *American Methyl* line of cases bars the agency from relying on its inherent reconsideration authority for the underlying substantial equivalence determination. In FDA's view, Ivy is conflating the underlying substantial equivalence determination with the potential consequence of that decision – classification into Class I, II, or III.

Although counsel for FDA has advanced a forceful case for the agency's position, we ultimately think that Ivy has the better of the argument. It may well be correct, as FDA contends, that the statutory procedures outlined in Sections 360c(f) (for determining substantial equivalence) and 360c(e) (for reclassification) are not mirror images of one another. But the fundamental question both provisions address – what is the appropriate classification of a new device? – is the same. And as a practical matter, the decision to revoke a substantial equivalence determination in circumstances like those present here is a de facto reclassification of the device

into Class III, at least absent other FDA action. If FDA finds that a device is no longer substantially equivalent to any existing Class I or Class II devices, that device is automatically reclassified as a Class III device. In other words, to revoke a substantial equivalence determination is to "change the classification," 21 U.S.C. § 360c(e)(2), of that device.

FDA's statutory reclassification authority covers the same concerns, and achieves the same result, as revocation of a substantial equivalence determination. Therefore, as in *American Methyl*, "Congress has provided a mechanism capable of rectifying mistaken actions," and 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 360c(e) 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.

In short, because FDA concededly could have used Section 360c(e) to reclassify the Collagen Scaffold into Class III, it could not rely on a claimed inherent reconsideration authority to short-circuit that statutory process and revoke its prior substantial equivalence determination to achieve that same result.

The practical significance of our holding on this point is limited but important. To reclassify under the statute, FDA must go through certain procedural hoops, including notice and comment. *See* FDA Br. 36. 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.[1]

III

FDA responds that even if Section 360c(e) is the kind of statutory provision that can displace inherent reconsideration authority, the *American Methyl* principle still would not apply on the particular facts of this case. *American Methyl* held that EPA had erred by failing to use the statutory procedure for revoking fuel-marketing waivers. But in a footnote, the Court also stated that it was not expressing any view "as to EPA's power to revoke a waiver obtained through fraud, ex parte contacts, or other misconduct tainting the original record and thereby affecting the integrity of an agency's proceedings." 749 F.2d at 834 n.51. The Court went on to note that in the case before it there was no evidence of such fraud or misconduct in the administrative record. *Id.*

[1] As both a legal and a practical matter, the difference between our approach and the dissent's approach is exceedingly narrow. As a legal matter, we simply read this particular statutory notice and comment scheme as one that, under our *American Methyl* precedent, negates FDA's resort to its inherent authority in these circumstances. As a practical matter, FDA can still quickly and readily reclassify a device even with notice and comment. Moreover, in certain situations where it becomes necessary, an agency may rely on exceptions to the notice and comment requirement. *See, e.g.*, 5 U.S.C. § 553(b)(3)(B).

Here, FDA argues that the findings of its internal investigation – political pressure, agency acquiescence to that pressure, and departures from standard agency procedures – are the kinds of concerns that *American Methyl* contemplated could warrant reconsideration on the basis of inherent authority even if a statutory reconsideration provision exists.

FDA overreads *American Methyl*. To begin with, it is not clear that *American Methyl*'s statements regarding the implications of misconduct are anything more than dicta. As FDA itself points out, the record in *American Methyl* contained no evidence of misconduct. The Court therefore had no occasion to consider whether a finding of misconduct would allow an agency to use inherent authority – rather than statutory authority – to reconsider a decision. Indeed, the Court explicitly stated that it "of course intimate[d] no view" on the subject. *Id.*; *see also id.* at 835 n.55 (fraud allegations "an issue not before us today and on which we venture no opinion"). Given its ambiguous precedential value, we are hesitant to bind ourselves to *American Methyl*'s supposed misconduct exception. *Cf. Empresa Cubana Exportadora de Alimentos y Productos Varios v. Department of Treasury*, 638 F.3d 794, 802 (D.C. Cir. 2011) (where footnote was arguably dicta, Court would "decline to elevate it now to a holding").

In any event, it is unnecessary to decide today whether to recognize that *American Methyl* exception. Even accepting that *American Methyl*'s footnote 51 created an exception for misconduct, that exception poses a high bar and would not apply in this case. To state the obvious, not every wrong decision or ill-considered decision is tainted by misconduct. The term "misconduct" as used in *American Methyl* connotes some clear legal or ethical violation. Here, the record indicates that the review process for the Collagen Scaffold was perhaps imperfect, but the supposed mistakes do not rise

to the level of misconduct contemplated by *American Methyl*. 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 Members' expression of their views – on both sides – was not misconduct for purposes of the *American Methyl* exception.

Similarly, while the report identified mistakes in the expert panel proceedings, the report found no evidence that those supposed defects affected FDA's decision. *See* FDA PRELIMINARY REPORT 20-21 (consequences of excluding review team members were "speculative" and panel transcript "does not provide adequate support for a conclusion that the integrity of the process was compromised").[2]

[2] The District Court expressed concern about purported ex parte contacts between FDA officials and ReGen's executives following the denial of ReGen's second premarket notification. *See Ivy Sports Medicine, LLC v. Sebelius*, 938 F. Supp. 2d 47, 57 (D.D.C. 2013). As Ivy points out, however, the statutes and FDA regulation barring companies from meeting with FDA officials apply only to formal, on-the-record hearings in a rulemaking or adjudication, not to informal agency proceedings, such as proceedings to determine substantial equivalence. *See* 5 U.S.C. § 557(a), (d); 21 C.F.R. § 10.55(a). And generally speaking, it is a good thing for agency officials to meet with regulated entities and other affected parties.

It is also notable that no senior leaders of FDA, executives of ReGen, or Members of Congress were disciplined for their involvement in the scaffold's review process. Yet if FDA actually rendered a decision tainted by misconduct – as opposed to simply reaching a mistaken decision or a decision it no longer agrees with – that misconduct must have been due to the legally or ethically wrongful actions of some person or persons. FDA's inability or unwillingness to identify those wrongdoers is an indication that, in fact, no *American Methyl*-level misconduct occurred, at least on the record before us.

* * *

Because Congress created a procedure for FDA to reclassify medical devices, FDA may not short-circuit that process through what it calls its inherent authority to reverse its substantial equivalence determinations for those devices. FDA's order rescinding the Collagen Scaffold's substantial equivalence determination on the basis of inherent authority was therefore invalid. We reverse the judgment of the District Court. We direct the District Court to vacate FDA's decision and to remand to the agency for further proceedings.

So ordered.

PILLARD, *Circuit Judge*, dissenting: This case requires us to consider the source and scope of the FDA's authority to rescind its clearance of an ineffective medical device when the agency concludes that its decision was flawed and that it should not have cleared the device in the first place. Ivy Sports Medicine's predecessor, ReGen Biologics,[1] developed a surgical mesh, referred to as the Collagen Scaffold, which it described as a resorbable, crescent-shaped mesh designed to be implanted inside the knee joint in treatment of injuries of the meniscus. The FDA cleared the device for marketing as a Class II device under the Federal Food, Drug, and Cosmetic Act, as amended by the Medical Device Amendments of 1976 (MDA) (collectively, FDCA or the Act). It did so without making any substantive determination that the device met the statutory Class II criteria, but by an alternative route that the statute authorizes: deeming the device substantially equivalent to other Class II surgical meshes already in use. In effect, the FDA's clearance of the Collagen Scaffold piggybacked on its prior approval of other, ostensibly equivalent "predicate" devices. But the FDA soon recognized that the apparent equivalence was specious and rescinded the Class II clearance because none of the predicate surgical meshes was used in a weight-bearing joint like the knee, nor was any used in place of diseased tissue. There was, moreover, no evidence that the Collagen Scaffold had any beneficial effect for its intended use.

Neither the erroneous clearance nor its reversal was accompanied by notice and comment rulemaking. Ivy acknowledges that the statute provides for substantial equivalence determinations to be made without notice and comment, but challenges the reversal because, in its view, the FDA lacks authority to revisit any erroneous equivalence decision except through the Act's notice-and-comment

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[1] For the sake of simplicity, this opinion refers interchangeably to both ReGen Biologics and Ivy Sports Medicine simply as "Ivy."

process for making "Classification Changes." Where a statute specifies an exclusive process for revoking erroneous decisions, agencies cannot circumvent that process by adverting to their inherent or implied power of error correction. Ivy contends that 21 U.S.C. § 360c(e) ("subsection (e)") is the exclusive process for revoking an erroneous substantial equivalence determination, and so ousts the FDA's implicit reconsideration authority.

The FDA argues to the contrary. The regulatory "Classification Changes" procedure, codified in subsection (e), is a means to adjust a device's statutory classification "based on new information respecting [the] device." It is narrower than Ivy supposes, and clearly does not set forth the exclusive process—and perhaps not even a permissible route—for revocation of the FDA's substantial equivalence determination.

The statute's text, structure, history, and purpose, in addition to past administrative practice, all show that the FDA permissibly read the statute not to displace its otherwise-undisputed implicit authority to correct erroneous substantial equivalence decisions. Subsection (e) speaks neither to correction of decisions that were wrong when made, nor to substantial equivalence determinations. It is keyed instead to changes in light of new information of classifications that were themselves made through a notice-and-comment process under subsections (b)-(d). *See* 21 U.S.C. § 360c(b)-(d). It does not relate to the type of *de facto* reclassification to Class III that occurs upon revocation of an erroneous clearance into a lower class under the substantial equivalence determination, and, indeed, does not speak to any decision, such as an equivalence revocation, that would move a device from Class II or I into Class III. It does, however, specifically

contemplate shifts in the opposite direction, e.g., out of Class III into Class II or I.

Congress did not intend subsection (e) to be the exclusive method to reconsider assessments of substantial equivalence, so it does not displace the FDA's implicit authority to correct its own errors. I believe the majority errs in reading the Act to require that the agency's erroneous approval of a medical device via the abbreviated substantial equivalence process remain frozen in place unless the agency takes the long way around, through notice and comment rulemaking required for "Classification Changes," to undo it, and so I respectfully dissent.

I. Background

As the majority explains, a medical device defaults to the restrictive "Class III" under the Act unless the FDA determines that it belongs in the less restrictive Class II or Class I (or affirmatively classifies it as required to remain in Class III). Ivy initially faced a choice of two routes by which it might have its device moved into a less restrictive class. One route was to petition the Secretary for classification of the device directly under the statutory criteria. The other way was to employ a shortcut "substantial equivalence" process. After an initial stab at developing the clinical evidence for a premarket approval application, Ivy chose to bypass the more onerous regulatory route and seek FDA clearance into Class II via the piggyback substantial equivalence process. Ivy thus filed a premarket notification contending that its device was substantially equivalent to a set of already-classified predicate devices. If that abbreviated process did not succeed, Ivy retained the option to seek clearance by petitioning the Secretary for application of the statutory criteria under the de novo classification process.

As it happened, the piggyback worked for Ivy, at least temporarily. The FDA approved the Collagen Scaffold as substantially equivalent to Class II surgical meshes that were already being marketed to reinforce injured soft tissue, such as a sutured rotator cuff or fistula. But the substantial equivalence determination was fraught and close. The FDA found equivalence reluctantly, and soon suspected that it had erred. The agency did not immediately reverse itself, however, but ordered an independent review of its process to determine whether it had improperly bowed to outside pressures. In addition, the agency organized a new FDA team to review the device's substantial equivalence, subject to further review by a panel of outside experts. The preliminary report of the internal investigation, titled "Review of the ReGen Menaflex®: Departures from Processes, Procedures and Practices Leave the Basis for A Review Decision in Question," identified significant process irregularities and concerns about outside pressures. The scientific review found no substantial equivalence due to the different technological characteristics and intended use from the predicate meshes and concluded that the Collagen Scaffold was not as safe and effective as the predicates. With the results of those investigations in hand, the FDA decided that the substantial equivalence determination was indeed wrong and reversed it, inviting Ivy to submit the device for a risk-based classification of the device through the de novo process. Instead of submitting the Collagen Scaffold for classification under the statutory criteria, however, Ivy filed suit under the Administrative Procedure Act challenging the FDA's authority to reconsider and revoke its own erroneous substantial equivalence determination.

Ivy argues that the FDA's reversal is invalid because, in its view, Congress required any correction of error in a substantial equivalence determination go through notice and

comment rulemaking, and the FDA's reversal here, however informed and procedurally careful, did not proceed by regulation. Ivy points to subsection (e), the Act's provision entitled "Classification Changes" that authorizes such changes by notice and comment rulemaking, and contends that the statute makes that provision the exclusive authority for reversal of erroneous substantial equivalence determinations because the effect of such a reversal is to return the device by default to Class III, and thus, effectively, to change its classification.

Subsection (e)(1) begins:

> Based on new information respecting a device, the Secretary may, upon his own initiative or upon petition of an interested person, by regulation (A) change such device's classification, and (B) revoke, because of the change in classification, any regulation or requirement in effect under section 360d or 360e of this title with respect to such device.

21 U.S.C. § 360c(e)(1).[2] The subsection goes on to provide that, in promulgating such a classification-change regulation, "the Secretary may secure from the panel to which the device was last referred pursuant to subsection (c) of this section [authorizing initial classification by regulation] a recommendation respecting the proposed change in the device's classification." *Id.* It then spells out conditions required for changing device classifications, referring only to changes from Class III to Class II or I, which the parties refer to as "down classification." It nowhere mentions substantial

[2] As discussed further below, subsection (e) was amended in July 2012. Unless otherwise noted, all citations to the Act refer to the provisions in effect when the FDA rescinded its substantial equivalence determination.

equivalence or the statutory provision authorizing equivalence determinations, nor does it mention changes in classification in the other direction (as occurred here), from Class I or II to Class III, referred to as "up classification."

II. Analysis

The sole issue here is whether the FDCA requires the agency to go through the rulemaking process authorized by subsection (e) for "Classification Changes" in order to undo an erroneous substantial equivalence determination, which it was not in the first instance required to make by rule, and which did not involve application of the Act's classification criteria. The nub of the dispute is a contest between dueling statutory implications. The FDA relies on the established principle that agencies' power to make decisions implies their power to reconsider and revoke erroneous decisions. Ivy acknowledges such implicit power of error correction, but contends that the FDCA eliminates it here by operation of the settled canon, *expressio unius est exclusio alterius*, i.e., the express mention of one thing excludes all others. Ivy says the statutory provision authorizing "Classification Changes" by regulation, 28 U.S.C. § 360c(e)(1), is the explicit and exclusive avenue for changing any agency decision that yields even a default, provisional reclassification of a medical device. Thus, according to Ivy, the FDA must conduct rulemaking under the "Classification Changes" provision, not only to change a classification initially determined by rulemaking under subsections (b)-(d), *see* 21 U.S.C. § 360c(b)-(d), but also to reverse a piggyback decision to clear a device under subsection (f) as substantially equivalent to a predicate device the FDA has already cleared, see *id.* § 360c(f)(1). As Ivy understands it, subsection (e) ousts by negative implication the authority the agency would otherwise have to reconsider and revoke, without conducting notice and

comment rulemaking, a non-regulatory substantial equivalence decision that it made in error.

The FDA counters that it need not conduct notice and comment rulemaking under subsection (e) to rethink and retract a substantial equivalence decision that it decides, on the original record, was wrong from the start. The FDA's inherent authority is preserved, it argues, because "neither the text nor the legislative history of [subsection (e)] speak to reconsideration or even to substantial equivalence at all." Br. for Appellees 30. And even if it can be read to bar reconsiderations triggered by "new information," such information being the threshold requirement of subsection (e), the FDA contends that it need not be used for revocation of decisions "that were flawed at their inception." *Id.*

The parties start from the shared premise that the FDA has implicit statutory authority to correct its own errors, including erroneous substantial equivalence decisions, unless subsection (e) displaces it. *See* Slip Op. 9-10. It is well settled that, even where Congress has provided no explicit mechanism for agency reconsideration, statutes that authorize agencies to act are also presumed to empower those agencies to reconsider their actions to correct their mistakes. *See, e.g.*, *Boesche v. Udall*, 373 U.S. 472, 476 (1963); *Civil Aeronautics Bd. v. Delta Air Lines, Inc.*, 367 U.S. 316, 325 (1961); *Am. Trucking Ass'ns v. Frisco Transp. Co.*, 358 U.S. 133, 145 (1958); *Nat'l Ass'n of Trailer Owners, Inc. v. Day*, 299 F.2d 137, 139 (D.C. Cir. 1962). "[I]n the absence of any specific [statutory] limitation," an agency retains authority to reconsider and correct an earlier decision. *Albertson v. FCC*, 182 F.2d 397, 399 (D.C. Cir. 1950). The description of such authority as "inherent," though widely used in our precedents, is somewhat of a misnomer, because the FDA, like other executive agencies, is "entirely a creature of Congress." *Civil*

Aeronautics Bd., 367 U.S. at 322. Assuming no "inherent" power in the constitutional sense, *cf. Owens v. Republic of Sudan*, 531 F.3d 884, 893 (D.C. Cir. 2008), agencies are typically understood to have statutorily implicit corrective powers in the absence of statutory provisions explicitly removing them. *See Civil Aeronautics Bd.*, 367 U.S. at 321-22. The touchstone, then, is congressional intent.

American Methyl Corp. v. EPA, 749 F.2d 826 (D.C. Cir. 1984), is a straightforward statutory interpretation decision, and Ivy's application of it here rests on a misreading of the FDCA. In *American Methyl*, the EPA asserted that it retained inherent authority to revoke a waiver granted under Section 211(f)(4) of the Clean Air Act that allowed the introduction of a fuel additive onto the market. *See id.* at 828-29. The court rejected the agency's assertion of inherent authority to revoke the waiver, concluding that Section 211(c) of the statute expressly "empowered [the agency] to take action against an offending fuel or fuel additive" that was "already in commerce," and that, because the statute explicitly set forth that process for taking a fuel additive off the market, the agency could not avoid it by resorting to its "inherent authority" to revoke the waiver. *Id.* at 835-366. Specifically, the court looked at the "interrelationship" of subsections (c) and (f) and concluded that Section 211(c) "provid[ed] a mechanism for correcting" the error in that case. *Id.* at 834-35; *see also id.* at 836-37 (analyzing "statutory design"). The court also examined the legislative history, emphasizing that it supported the view that Congress intended Section 211(c) "as the *exclusive means* by which [the agency] was to correct waivers mistakenly granted by default." *Id.* at 836 (emphasis added). Because "Congress contemplated regulation of fuels and fuel additives . . . waived into commerce *only* through proceedings under section 211(c)," the court reasoned that "the legislative understanding thus rejects the implied

revocation authority claimed by the EPA." *Id.* at 834 (emphasis added)). Explicit authority must be used where it represents an exclusive and specific limitation on whatever inherent authority the agency might otherwise have had. *Albertson*, 182 F.2d at 399-400; *Am. Methyl*, 749 F.2d at 835.

As *American Methyl* recognizes, the touchstone in determining whether an explicit provision must be read to limit an agency's implied authority to reconsider a prior decision is whether "Congress had an intention on the precise question at issue." *Am. Methyl*, 749 F.2d at 833 (quoting *Chevron, U.S.A., Inc. v. Nat'l Resources Defense Council, Inc.*, 467 U.S. 837, 843 n.9 (1984)). The "precise question" in this case is whether Congress intended subsection (e), which allows the FDA to make a "classification change" by regulation, to be the exclusive means for the agency to reconsider a substantial equivalence determination. Answering that question requires examination of the statutory scheme, *see id.* at 834-37, guided by "the customary statutory interpretation tools," *Cal. Metro Mobile Commc'ns, Inc. v. FCC*, 365 F.3d 38, 44 (D.C. Cir. 2004) ("traditional tools" include text, structure, purpose, and legislative history); *see also Am. Methyl*, 749 F.2d at 834-837 (reviewing legislative history, text, structure, and agency practice). Read with the help of those customary tools of statutory interpretation, the FDCA makes clear that Congress never intended to require the FDA to use subsection (e) to rescind an erroneous substantial equivalence determination.

A. Statutory Overview

Some statutory context is helpful to explicate the textual, structural, and functional relationship between the full regulatory classification process detailed in subsections (b)-(d) and the shortcut subsection (f) substantial equivalence

determination. *Compare* 21 U.S.C. § 360c(b)-(d), *with id.* § 360c(f). Congress enacted the MDA in 1976 to bring medical devices, not previously subject to federal regulation, under the ambit of the FDCA. The new regulatory scheme was designed to give consumers prompt access to medical devices beneficial to human health while keeping off the market devices that are not safe and effective. *See Contact Lens Mfrs. Ass'n v. FDA*, 766 F.2d 592, 593-94 (D.C. Cir. 1985). The Act grants authority to the agency to classify medical devices into three classes "based on the risk that they pose to the public." *Medtronic Inc. v. Lohr*, 518 U.S. 470, 476 (1996); *see Contact Lens Mfrs. Ass'n*, 766 F.2d at 594. As the majority explains, a device's classification determines both the relative ease with which the device can enter the market and the types of marketing restrictions to which it will be subject, with devices in Class III requiring the FDA's affirmative premarket approval, subject to the most extensive conditions, and those in Classes II and I subject only to specific or general controls. *See* 21 U.S.C. § 360c(a)(1); Slip Op. at 3. No medical device introduced after the enactment date of the MDA may be marketed until the FDA has at least acted to clear it. The FDA treats such a device as Class III by default unless and until it moves it into a lower category, such as by application of the statutory criteria, *see id.* § 360c(f)(2)-(3), or a substantial equivalence determination under subsection (f)(1).[3]

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[3] Class III devices may not be marketed without premarket approval, whereas devices in Class II and Class I need no such additional scrutiny. A premarket approval application initiates a detailed process of scientific review requiring the manufacturer to submit research findings showing the device is safe and effective for its intended use, together with proposed labeling that is not false or misleading. *See* 21 U.S.C. § 360e. The FDA's premarket approval process involves referral of the device to expert panels,

The majority is correct that, in practice, placement of a new device in Class I or II usually is obtained through a determination that the device is "substantially equivalent" to a predicate device, i.e., one already in Class I or II. But the majority misunderstands subsection (e) in part because it leaves out of its description a number of related provisions of Section 360c ("Classification Of Devices Intended For Human Use") that describe the Act's foundational method of device classification by regulation, informed by recommendations from panels of scientific experts and subject to public notice and comment. *See* 21 U.S.C. § 360c(b)-(d). Reading Section 360c as a whole makes clear that the subsection (e) process is required not for revocations of piggyback substantial equivalence determinations, but for changes in classifications initially made by the foundational regulatory classification route.

When Congress enacted the MDA to bring medical devices under the ambit of the FDCA, it faced the project of classifying an enormous number of then-existing medical devices (now commonly referred to as "pre-amendments devices"). Subsections (b)-(d) require that to be done through a process of notice and comment rulemaking, supported by input from expert advisory panels, to determine with respect to each type of device its effectiveness and the risks it poses, and what kinds of controls might be needed for it be used as

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and inspection of the manufacturing site and assurances about the manufacturing process. Throughout the premarket approval process, the burden of proof is on the manufacturer. Approval, when given, is typically accompanied by marketing conditions to provide reasonable assurance of safety and effectiveness. *See id*. § 360e(c)-(d). The time and cost associated with the premarket approval process tends to motivate manufacturers to seek classification of their devices into Class I or II where it is feasible to do so. *See Medtronic*, 518 U.S. at 479.

intended in a safe and beneficial manner. *See* 21 U.S.C. § 360c(b)-(d). The Act provides—in subsection (e), on which Ivy relies—that, where new information respecting a device comes to the FDA's attention, the agency must again deploy notice and comment rulemaking if it wants to change the device's classification. *Id.* § 360c(e). Pre-amendments devices are grandfathered and thus left unclassified unless and until the FDA classifies them pursuant to subsection (a)-(d). *See Medtronic*, 518 U.S. at 477-78.

Congress further created, in subsection (f), a dual-track process to be followed to clear new, or "post-amendments" devices. Whereas the default for pre-amendments devices is that they are left unclassified until classified, subsection (f) starts all post-amendments devices in Class III by default, and then sets forth two tracks for their clearance for marketing. One track involves FDA application of the statutory criteria to post-amendments devices through a rulemaking process analogous to that used for pre-amendments devices. Thus, if a new device has no apparent equivalent among cleared predicate devices, for example, it can be cleared like a pre-amendments device, through a process that may include expert panels and is subject to notice and comment. *See* 21 U.S.C. § 360c(f)(3).

The other track piggybacks on the foundation of devices classified by regulation, by simply matching new devices to those already-reviewed predicates as a way to assign them to their appropriate classes. *See id.* § 360c(f)(1). That second, expedited clearance process applies to post-amendments devices that are "substantially equivalent" to already cleared devices to avoid shielding devices already in use from competition from new and potentially improved versions. *See id.*; *Medtronic*, 518 U.S. at 478. The substantial equivalence inquiry does not require the FDA to apply the statute's

classificatory criteria to the new device, but asks whether the new device is substantially equivalent to a predicate device and thus can be assigned the same classification. *See id.* § 360c(i) (defining substantial equivalence). The substantial equivalence decisional process is a procedural as well as substantive shortcut, as it does not require notice and comment rulemaking. *See id.* § 360c(f)(1).

Finally, subsection (f) provides that proponents of post-amendments devices can have it both ways: When a manufacturer or importer tries the substantial equivalence shortcut and fails, the device defaults back to Class III, *see id.* § 360c(f)(1), but that need not be the end of the road. If, for example, the FDA rules adversely on a petition for substantial equivalence because the device has a different intended use from the predicate, the unsuccessful petitioner can within 30 days request that the Secretary classify the device as safe and effective in its own right under a de novo process applying the statutory criteria. *See id.* § 360c(f)(2).

B. Statutory Text

In discerning Congress's meaning, the text is primary. Subsection (e) authorizes the FDA, on its "own initiative or upon petition of an interested person, by regulation," to change a device's classification. 21 U.S.C. § 360c(e)(1). The parties agree that "by regulation" means notice and comment rulemaking. The question is whether Congress intended subsection (e) to be the exclusive process for reconsidering erroneous substantial equivalence determinations. The statute's text shows that it did not and, indeed, raises doubts about whether it would have even been permissible for the agency to use it for that purpose.

1. Subsection (e) explicitly addresses subsection (c) classification, not subsection (f) substantial equivalence.

The first hint that subsection (e) does not restrict the agency's reconsideration of erroneous substantial equivalence determinations is that subsection (e) makes no reference to the piggyback substantial equivalence process or the provisions codifying it, whereas it explicitly cross-references the full regulatory process for classifying devices by application of the statute's classification criteria, with input from expert advisory panels and notice and comment. As Ivy's counsel acknowledged during oral argument, Congress developed subsection (e) as a procedural mechanism for reclassifying pre-amendments devices. *See* Oral Arg. Rec. at 4:45-4:55 (counsel for Ivy) (describing rulemaking procedures for pre-amendments devices and explaining that "Congress initially provided for reclassification of pre-amendments devices by notice and comment rulemaking [i.e. via subsection (e)] to parallel that original classification decision"). Subsection (e) specifically cross-references the classification procedures for *ab initio* regulatory device classification: It empowers the FDA to "secure from the panel to which the device was last referred pursuant to [the rulemaking procedures for pre-amendments devices] a recommendation respecting the proposed change in the device's classification." *Id.* § 360c(e)(1) (citing § 360c(c)). Mirroring the requirements of the regulatory classification procedures (set forth in subsections (b)-(d)), subsection (e) requires that any panel recommendation for a classification change must likewise be published in the Federal Register. *Compare id.* § 360c(d)(1), *with id.* § 360c(e)(1). The explicit statutory cross-reference and the parallel procedures reflect Congress's assumption that the device classifications subject to change under subsection

(e) are those that were made in the first instance, with expert panel input, pursuant to subsections (b)-(d).

The text of subsection (e) makes no mention whatsoever of subsection (f) or substantial equivalence determinations. Because classifications that result from substantial equivalence determinations, unlike those made under subsections (b)-(d), do not proceed by panel recommendation and notice and comment rulemaking, subsection (e)'s textual reference to subsection (c) and "the panel to which the device was last referred" make no sense in the context of revocation of a substantial equivalence determination, such as is at issue in this case. Subsection (e)'s explicit references to the panel process, and its lack of any mention of either error correction or substantial equivalence, belies Ivy's efforts to cast it as the only way the FDA can correct an equivalence decision it recognizes was wrong.

2. Subsection (e) speaks to classification changes based on new evidence, not correction of errors in an initial substantial equivalence determination.

Two additional textual features reinforce the conclusion that subsection (e) is not the FDA's exclusive means to revoke an invalid substantial equivalence determination: Subsection (e) is titled "Classification Changes," and provides for changes in response to "new information respecting a device." Neither of those terms is apposite to revocation of equivalence decisions that were invalid at their inception.

The FDA asserts here the authority to reconsider a decision on its initial record, not to change it based on new information. The agency's reversal of its determination that the Collagen Scaffold was equivalent to predicate devices—like any determination that the agency made the wrong equivalence decision from the start—was not triggered by any

"new information," and yet such information is the threshold condition for application of subsection (e).[4]

It is also not at all clear that, even if it were triggered by new information, reversal of a substantial equivalence determination is a "classification change" within the meaning of subsection (e). Revoking the decision that the Collagen Scaffold was substantially equivalent to devices in Class II caused a *de facto* "change" in its "classification" back to Class III, but that change resulted from the statutory default that places all post-amendments devices in Class III until the FDA takes appropriate action on them. 21 U.S.C. § 360c(f)(1). The Collagen Scaffold moved back to Class III only provisionally and by default, and not as the result of any affirmative classification decision based on new information, such as subsection (e) contemplates.

3. Subsection (e) refers only to changes from more to less restrictive classifications, but invalidating an erroneous equivalence determination has the opposite effect.

Subsection (e) provides further textual indication that it does not apply to the kind of *de facto* classification change here, resulting from operation of the statute's default

[4] The FDA has read "new information" to also encompass the reevaluation of existing information. J.A. 1675; *see, e.g., Medical Devices; Reclassification of the Cutaneous Carbon Dioxide and the Cutaneous Oxygen Monitor*, 67 Fed. Reg. 76,678, 76,679 (2002) (citing, *inter alia*, *Holland Rantos v. U.S. Dep't of Health, Educ., & Welfare*, 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978)). That is not contrary to the point that Congress tied subsection (e) to evidence-based classifications based on the statutory criteria, not to rescissions of substantial equivalence determinations that were void on the record information from the start.

placement of post-amendments devices in Class III: It refers only to what the parties call "down classifications" (e.g., from Class III to Class II or I) and not to "up classifications" (e.g., from a lower class back up to Class III). Subsection (e) thus is not the requisite process for all reclassifications, as Ivy implies, but specifically governs moving Class III devices to lower classifications under certain circumstances. *See id.* § 360c(e)(2)(A) (referring to classification change from Class III to Class II); *id.* § 360c(e)(2)(B) (referring to classification change from Class III to Class I). Under subsection (e), the FDA may change a device's classification from Class III to Class I or Class II if the agency determines that the controls provided by the lower classification "would provide reasonable assurance of the safety and effectiveness of the device." 21 U.S.C. § 360c(e)(2)(A) & (B). By contrast, in this case as in any case of substantial equivalence, the FDA did not have to consider the ability of classification controls to assure safety and effectiveness; rather, the agency simply determined—based on an evaluation of the device's intended use and technological characteristics—that the Collagen Scaffold was not substantially equivalent to the predicate devices that the manufacturer had identified. *See* Oral Arg. Rec. at 28:53-31:21.

Based on its explicit reference to down classifications only, it is far from obvious why the plain text of subsection (e) even permits, much less mandates, that the agency use it to upclassify the Collagen Scaffold. *See* Oral Arg. Rec. at 25:55-26:15 (counsel for FDA) (asserting the agency's up-classification authority but acknowledging that the question has not been adjudicated by any court).[5] Neither of the types

[5] After the events at issue here, Congress prospectively amended subsection (e) to provide that it may be used to "up classify" devices from Class II to III. Food and Drug Administration Safety & Innovation Act, Pub. L. No. 112-144, § 608, 126 Stat. 993, 1055-

of reclassifications specifically enumerated in subsection (e) (from Class III to II, or from Class III to I) describes the effect of the FDA's rescission of the substantial equivalence determination, which restored the Collagen Scaffold from Class II to the default, more closely restricted, Class III.

C. Statutory Structure and Purpose

The structure of the statute reinforces the textual evidence that Congress intended subsection (e) to play a different and more limited role than Ivy contends. A key structural feature of the Act is subsection (e)'s placement in the statute, which reinforces the distinction between the foundational classification of devices via a regulatory process of determining their safety and effectiveness, and the dependent process of classification based on matching new devices with predicates already on the market. The second, procedurally abbreviated, process piggybacks on the first process, which relies on expert panels and notice-and-comment rulemaking. Subsection (e) appears immediately after those subsections that set forth the regulatory classification process, but before subsection (f), which sets forth the piggyback classification method. Thus, the procedure that Ivy says must control rescission of an erroneous substantial equivalence determination appears in the statute before the FDCA defines or even mentions "substantial equivalence." *See* 28 U.S.C. § 360c(f)(A)(ii). It seems unlikely that Congress codified a

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56 (2012) (amending 21 U.S.C. § 360c(e)(1) to permit reclassification from Class II to III when Class I and II controls "together are not sufficient to provide a reasonable assurance of safety and effectiveness for such device"). As the majority emphasizes, the FDA has taken the position that, even prior to its amendment, the agency *could* have used subsection (e) to reclassify the Collagen Scaffold into Class III. That contention is addressed below.

mechanism for correcting a type of determination before it codified the authority for making such determination in the first place. Subsection (e) more logically relates not to substantial equivalence determinations, but to the full-dress device-classification provisions set forth in subsections (b)-(d)—to which it expressly refers and which immediately precede it in the statute. Structurally, it makes sense that subsection (e) explains how to change the type of *ab initio* classification described in the immediately preceding subsections of the statute; it is much less logical to conclude that it governs undoing a different kind of decision that the statute does not even set forth until later.

That conclusion is further reinforced by the equal rigor of the processes required to classify a device under subsections (b)-(d) and to change its classification under subsection (e), both of which require notice and comment rulemaking. For example, just as pre-amendments classifications must be announced "by regulation," so too a classification change under full-dress reclassification must be effectuated "by regulation." *Compare* 21 U.S.C. § 360c(d)(1) (initial classification), *with id.* § 360c(e)(1) (classification changes). That symmetry contrasts with the very different, shortcut process contemplated for substantial equivalence decisions under subsection (f)(1). *Id.* § 360c(f)(1). The latter type of decisions bypass the statutory classification criteria and instead focus on matching a new device with a cleared predicate, and do not require notice and comment rulemaking.

It makes practical sense that decisions made through the time consuming and expensive rulemaking process cannot be lightly changed—hence the notice and comment requirement in subsection (e) for classifications changes, which mirrors the process in subsection (d) for the classifications thereby being changed. In contrast, classifications made by deciding

into which of several boxes to place a new device (where the boxes are the prior device classifications) typically are—and are intended to be—quicker and more informal. *Cf. Medtronic*, 518 U.S. at 478-79 (contrasting the roughly 20 hours needed to complete the "limited form of review" required for substantial equivalence with the 1,200 hours needed to complete a premarket approval).

Reading the statute so as not to require the subsection (e) process be used to correct erroneous substantial equivalence determinations best serves the statute's purpose. Congress enacted the FDA classification system to make sure that consumers benefit from safe and effective medical devices and are protected from those that are useless or unsafe. *See id*. at 475-77. The substantial equivalence process helps to preserve market competition in medical devices by removing unnecessary barriers that the classification process could pose to devices that are substantially equivalent to, and may be cheaper or better than, those that are already on the market. *See id.* at 478.

The court has it backwards in citing the accuracy benefits of notice and comment in support of Ivy's view, *see* Slip Op. at 12-13: Substantial equivalence decisions are prone to error in part because *they* are made *without* notice and comment, so Ivy's contention that notice and comment, admittedly not required for the initial equivalence decision, is necessary to fix such a decision if it was wrong creates an obstacle against correction of mistakes in a body of presumptively error-prone decisions. I read the Act to allow equivalence decisions to be reversed as readily as they are made (leaving open to a device manufacturer or importer to seek a more fully informed and thus accurate consideration of the device through the de novo process), which I believe better serves the Act's purpose of assuring the safety and effectiveness of medical devices than

does the one-way ratchet that Ivy advocates. The harms likely to flow from reading the Act so that mistaken equivalence determinations are easier to make than to fix are likely to be multiplied, because devices cleared as substantially equivalent thereby qualify as predicate devices for future equivalence decisions. An uncorrected error in deeming a device substantially equivalent invites a daisy chain of further errors. The court's holding that FDA must undertake the relatively formal, slow, and costly process contemplated by subsection (e) in order to correct errors in relatively quick and informal substantial equivalence determinations creates an unwarranted asymmetry, making erroneous approvals easy to make and cumbersome and slow to correct—a result that is at odds with the core aims of the Act.

D. Agency Practice

The text and structure of the Act are sufficient, standing alone, to demonstrate that Congress did not intend full-dress reclassification to be the exclusive statutory mechanism for the agency's reconsideration of an erroneous substantial equivalence determination. Nevertheless, because this court in *American Methyl* considered prior administrative practice relevant to the strength of the agency's statutory reading, *see* 749 F.2d at 838-39, it is worth briefly mentioning the FDA's prior practice. In *American Methyl*, the agency's own prior practice belied its proffered statutory analysis, *see id.* at 838, but here the FDA's practice is consistent with its position that a classification change by regulation is not the exclusive method for reconsidering a substantial equivalence determination. Indeed, as discussed below, it may not be an appropriate method at all.

Two aspects of the FDA's practice are especially pertinent. First, with respect to the rescission of prior substantial equivalence determinations, the FDA represented that there have been approximately 50 agency rescissions of substantial equivalence determinations in the history of the program, and that none of those has been accomplished using the regulatory classification change process of subsection (e). *See* Oral Arg. Rec. at 31:25-33:38. That further distinguishes this case from *American Methyl*, where "the agency's prelitigation administrative practice belie[d] its professed belief in an implied revocation authority." 749 F.2d at 838. We noted there that, "[i]n seven years of administering section 211(f), American Methyl [was] the first manufacturer subjected to a revocation proceeding" based on the EPA's asserted inherent authority; in every prior case the EPA had used the statute's express "control or prohibition" authority, *id.*, and we concluded that course of conduct "exemplified the understanding" of the statute we adopted there to oust any residual reconsideration power and restrict the agency to the "control or prohibition" provision, *id.* at 838-39.

Second, the FDA emphasizes—and Ivy does not dispute—that the agency rarely uses the regulatory reclassification authority to reclassify a single device, but rather uses it to change the classification of groups of devices. *See* Oral Arg. Rec. at 5:40-6:44, 31:25-33:38. The pending reclassification proceeding relating to transvaginal meshes (on which Ivy relied in its opening brief and again brought to the court's attention after oral argument) underscores that point. As the government explains, the FDA is currently using the subsection (e) reclassification procedure, including soliciting recommendations from an expert panel, to change the classification of two types of surgical meshes that encompass more than 100 different devices cleared over the course of 20 years. *See* 79 Fed. Reg. 24,634, 24,636 (May 1, 2014). The

consistent practices of not using subsection (e) to correct errors in substantial equivalence determinations, and using it to accurately build the foundational classification architecture of types of devices on which substantial equivalence decisions piggyback, lend support to the agency's position that it was not required to use the subsection (e) regulatory process to correct the mistaken equivalence decision about a single device in this case.

E. FDA's Assertion That It Could Have Used Subsection (e)

Ivy places substantial weight on the FDA's acknowledgement that, although the agency chose not to do so, it could have used the subsection (e) regulatory route to move the Collagen Scaffold from Class II to Class III. In Ivy's view, that concession all but clinches the case, on the logic that, if subsection (e) is available to move the device from Class II to Class III, under *American Methyl*, subsection (e) ousts implicit authority to correct an error by any other route. The court accepts that argument as decisive. It concludes that, because the FDA "concededly could have used [full-dress reclassification] to reclassify the Collagen Scaffold into Class III, it could not rely on a claimed inherent reconsideration authority to short-circuit that statutory process and revoke its prior substantial equivalence determination." Slip Op. at 12 (citing *American Methyl*).

That conclusion is in error for two related reasons. First, for the reasons discussed above, subsection (e) does not appear to apply at all to the kind of error-correction at issue in this case. And, second, even if the agency *could* have acted under subsection (e) to change the classification of the Collagen Scaffold, as the FDA contends, *American Methyl*'s negative implication would only apply here to displace the

FDA's implicit authority if the only permissible reading of the Act is that subsection (e) is the *exclusive* means for rescinding an erroneous substantial equivalence determination. The agency vigorously contests that point, and it has the better of the argument.

There is some question whether the FDA is correct that it could have used the subsection (e) process had it so chosen. As noted above, the revocation of the substantial equivalence determination was not "[b]ased on new information respecting [the] device," as subsection (e) expressly requires; it effected a "classification change" only by default, and it was an up classification whereas subsection (e) only addresses down classifications; and it addressed a decision not previously made with input from a panel convened under subsection (c), and thus was not the kind of decision subsection (e) describes.

Assuming it were available to the FDA to change the device's classification under subsection (e), that route would have effected an affirmative, regulatory "classification" decision. The route the FDA took, in contrast, merely reversed the agency's erroneous substantial equivalence determination, leaving to Ivy, if it so chose, to petition to classify the Collagen Scaffold under the statutory criteria for Class II. *See* 21 U.S.C. §§ 360c(f)(1)(B) & (C), (f)(2), (f)(3); J.A. 1317-18 (notifying Ivy of FDA's reversal of its substantial equivalence determination and inviting it to petition for Class II). In effect, what the FDA did left to Ivy whether to use the statutory-criteria regulatory classification process; all the agency did was to undo its error in having equated the device to an existing, already classified predicate device. It is consonant with the statute's structure and purposes for the FDA to conclude that it would have been authorized, had it so chosen, to take an alternative course of

not only undoing its error, but going on to apply the statute's criteria affirmatively to make a classification decision.

In any event, the FDA chose not to invoke the subsection (e) process here. My view of the statute does not rely on whether the agency was correct that it could have done so. It is at least clear that, even if the subsection (e) process were available to the FDA to initiate a full regulatory reclassification process to assess the propriety of the Collagen Scaffold remaining in Class II, that process is not required where the agency chooses simply to rescind a substantial equivalence decision it made in error without initiating any affirmative regulatory classification process such as subsection (e) provides.

III. Conclusion

The text and structure of the Act, along with the agency's administrative practice, amply support the FDA's interpretation as not confining the agency to the notice and comment process set forth in subsection (e) when it acts to rescind a substantial equivalence decision it made in error. The preceding analysis of subsection (e) shows that the *expressio unius* canon that the *American Methyl* court invoked in rejecting the agency's claim of implicit authority in that case does not apply to correction of a substantial equivalence determination that was erroneous from the start. *See* 749 F.2d at 835-36; *cf. Adirondack Med. Ctr. v. Sebelius*, 740 F.3d 692, 697 (D.C. Cir. 2014) (emphasizing that "the canon's relevance and applicability must be assessed within the context of the entire statutory framework"). That is especially true where, as here, a more plausible understanding is that Congress intentionally created two classification tracks—*ab initio* regulatory classifications, and the substantial equivalence shortcut—with separate procedural and

substantive requirements, and that subsection (e) addresses only the first track. *See Nat'l Shooting Sports Found., Inc. v. Jones*, 716 F.3d 200, 211 (D.C. Cir. 2013) (no application of *expressio unius* where its invocation "disregards other plausible explanations for an omission" (brackets and internal quotation marks omitted)).

A conclusion that the full-dress reclassification procedure did not preclude the FDA from exercising its implicit statutory authority to rescind the Collagen Scaffold's substantial equivalence determination would not mean that the FDA's exercise of that authority was reasonable in this case. *See Mazaleski v. Treusdell*, 562 F.2d 701, 720 (D.C. Cir. 1977). The parties disagreed on that point in the district court, but because Ivy did not renew those arguments until its reply brief, I would affirm the district court's conclusion on that point. *See New York Rehab. Care Mgmt., LLC v. NLRB*, 506 F.3d 1070, 1076 (D.C. Cir. 2007) ("[W]e have generally held that issues not raised until the reply brief are waived." (internal quotation marks omitted)).

Because all these reasons lead me to conclude that the FDA permissibly read section (e) not to displace its authority to revoke its mistaken clearance of the Collagen Scaffold without undertaking full notice and comment rulemaking, I respectfully dissent.