UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA *Plaintiff*, v. EDWARDS LIFESCIENCES CORP. and GENESIS MEDTECH GROUP LIMITED *Defendants*.	Civil Action No.

COMPETITIVE IMPACT STATEMENT

In accordance with the Antitrust Procedures and Penalties Act, 15 U.S.C. § 16(b)–(h) (the "APPA" or "Tunney Act"), the United States of America files this Competitive Impact Statement related to the proposed Final Judgment filed in this civil antitrust proceeding.

I. NATURE AND PURPOSE OF PROCEEDINGS

On July 13, 2026, the United States filed a Complaint against Defendants Edwards Lifesciences Corp. ("Edwards") and Genesis Medtech Group Limited ("Genesis") related to Edwards' acquisition of JC Medical, Inc. ("JC Medical") and Edwards' investment in Genesis. The Complaint alleges that Defendants violated Section 7A of the Clayton Act, 15 U.S.C. § 18a, commonly known as the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (the "HSR Act").

The Complaint alleges that Edwards acquired JC Medical from Genesis, through a transaction in excess of the then-applicable statutory threshold, without observing the required HSR Act waiting period. The HSR Act provides that "no person shall acquire, directly or

indirectly, any voting securities of any person" exceeding certain thresholds until that person has filed pre-acquisition notification and report forms with the Federal Trade Commission ("FTC") and the Department of Justice (collectively, the "federal antitrust agencies" or "agencies") and the post-filing waiting period has expired. 15 U.S.C. § 18a(a). A key purpose of the notification and waiting period is to protect consumers and competition from potentially anticompetitive transactions by providing the agencies an opportunity to conduct an antitrust review of proposed transactions before they are consummated.

At the same time the Complaint was filed, the United States also filed a Stipulation and proposed Final Judgment. Under the proposed Final Judgment, which is explained more fully below, Defendant Edwards (which now includes JC Medical) is required to pay a civil penalty to the United States in the amount of $10,000,000, and Defendant Genesis is required to pay a civil penalty to the United States in the amount of $2,000,000. Defendant Edwards must also notify the FTC before engaging in certain transactions and must institute an antitrust compliance program. The proposed Final Judgment is designed to deter HSR Act violations by Edwards and Genesis and similarly situated persons.

The United States and Defendants have stipulated that the proposed Final Judgment may be entered after compliance with the APPA. Entry of the proposed Final Judgment will terminate this action, except that the Court will retain jurisdiction to construe, modify, or enforce the provisions of the proposed Final Judgment and punish violations thereof.

II. DESCRIPTION OF THE EVENTS

A. Edwards' acquisition of JC Medical

In early 2024, Edwards began negotiating to acquire JC Medical from Genesis. In April 2024, Edwards and Genesis began discussing the possibility of Edwards making an investment in Genesis in addition to acquiring JC Medical. On July 22, 2024, Edwards acquired JC Medical for $115 million and future milestone payments with an ostensible value of approximately $1.8 million. On August 9, 2024, Edwards acquired non-voting shares in Genesis for $25 million.

B. Defendants' alleged violation of Section 7A

The HSR Act requirements apply to a transaction if, as a result of the transaction, the acquirer will hold assets or voting securities valued above the thresholds. Under HSR Rule 801.90, "[a]ny transaction(s) or other device(s) entered into or employed for the purpose of avoiding the obligation to comply with the requirements of the act shall be disregarded, and the obligation to comply shall be determined by applying the act and these rules to the substance of the transaction." 16 C.F.R § 801.90. Thus, under the Act, parties must make an HSR Act filing and observe a waiting period if they have used a transaction or other device to avoid the filing requirements and the substance of the transaction is reportable.

By April 2024, Edwards had indicated its interest in keeping the acquisition price below the HSR threshold, which at the time was $119.5 million. Edwards was concerned that HSR review would significantly delay the transaction. At the same time, unbeknownst to JC Medical and Genesis, Edwards was negotiating to acquire JenaValve Technologies, Inc. ("JenaValve"). Because JC Medical and JenaValve were the only two companies conducting clinical trials for a transcatheter aortic valve replacement for aortic regurgitation ("TAVR-AR") device in the

United States, the acquisition of both raised antitrust concerns that likely would have led both transactions to be investigated by the FTC, delaying both transactions.

Documents and testimony show that Edwards wanted to avoid filing under HSR for the acquisition of JC Medical. However, Genesis valued JC Medical at $125-150 million, and Genesis was unwilling to accept an offer below the HSR threshold. Thus, in April 2024, JC Medical proposed that, in addition to paying $115 million plus milestone payments for the voting securities of JC Medical, Edwards would make a contemporaneous investment of $10-35 million in Genesis to close the gap.

Edwards and Genesis intended the Genesis investment to be additional compensation to Genesis for the sale of JC Medical to Edwards that was "within the deal structure[,]" but—in the parties' view—did not count for HSR purposes. A sufficient part of the $25 million Genesis investment is attributable to additional compensation for JC Medical that, when added to the $115 million direct payment and milestone payments, the total price paid for the acquisition of JC Medical was above the then-HSR filing threshold of $119.5 million. Accordingly, the substance of the transactions between Edwards and Genesis was subject to the HSR filing requirements. However, Edwards and Genesis did not file under HSR and did not observe the waiting period requirements of the HSR Act. Instead, on July 22, 2024, Edwards and Genesis consummated the JC Medical acquisition.

III. EXPLANATION OF THE PROPOSED FINAL JUDGMENT

The relief required by the proposed Final Judgment will prevent future violations of Section 7A of the Clayton Act of the type Defendants committed and secures a monetary civil penalty for Edwards' and Genesis' violation of Section 7A. For Edwards, the proposed Final

Judgment sets forth prohibited conduct, a compliance program Edwards must follow, and procedures available to the United States to determine and ensure compliance with the Final Judgment. The Final Judgment will expire as to Defendant Edwards five years after the entry of the Final Judgment. The Final Judgment will expire as to Defendant Genesis upon payment of the civil penalty.

A. Prohibited Conduct

Section VI of the proposed Final Judgment is designed to prevent future HSR Act violations of the sort alleged in the Complaint. Edwards must notify the FTC before acquiring any part of a firm that is selling or conducting clinical trials in the United States for a TAVR-AR device. After notifying the FTC, Edwards must wait a specified amount of time, which can be extended by the FTC, before it can close on the acquisition. This requirement applies to transactions where Edwards does not have to comply with the notification and waiting period requirements of the HSR Act, including transactions that do not meet the size of transaction test under the HSR Act. This will prevent a recurrence of what happened in this case, where Edwards deliberately kept the nominal size of the transaction below the HSR Act threshold in order to avoid review by the FTC. The injunction is intended to broadly cover Edwards' conduct in this matter and prevent recurrence.

B. Compliance

Sections VII and VIII of the proposed Final Judgment set forth various compliance procedures. Section VII sets up an affirmative compliance program directed toward ensuring compliance with the limitations imposed by the proposed Final Judgment and with the federal antitrust laws. The compliance program includes the designation of an internal antitrust

compliance officer who is required to ensure that Edwards distributes a copy of the Final Judgment to each current and succeeding director, officer, employee, agent, or other person with the responsibility over sales, marketing, strategic planning, exploration and development, or mergers and acquisitions; briefs each such person regarding compliance with the Final Judgment and the antitrust laws as they apply to Edwards' activities; and obtains certification annually from each such person that he or she understands his or her obligations under the Final Judgment and agrees to abide by its terms. Section VII of the proposed Final Judgment further requires Edwards to certify to the United States that Edwards is in compliance and to report any violations of the Final Judgment.

To facilitate monitoring of Edwards' compliance with the Final Judgment, Section VIII grants DOJ access, upon reasonable notice, to Edwards' records and documents relating to matters contained in the Final Judgment. Edwards must also make its personnel available for interviews or depositions regarding such matters. In addition, Edwards must, upon request, prepare written reports relating to matters contained in the Final Judgment.

C. Civil Penalties

The proposed Final Judgment imposes a $10,000,000 civil penalty on Edwards and a $2,000,000 on Genesis for Defendants' violation of the HSR Act. The United States adjusted the penalty downward from the maximum permitted under the HSR Act in part because the Defendants were willing to resolve the matter by consent decree and avoid a prolonged investigation and litigation. The relief will have a beneficial effect on competition because it will deter future instances in which parties seek to avoid filing the required pre-acquisition notifications with the agencies and observing the required waiting period under the HSR Act by

artificially keeping the nominal price below the HSR Act threshold. At the same time, the penalty will not have any adverse effect on competition.

IV. REMEDIES AVAILABLE TO POTENTIAL PRIVATE LITIGANTS

There is no private antitrust action for HSR Act violations; therefore, entry of the proposed Final Judgment will neither impair nor assist the bringing of any private antitrust action.

V. PROCEDURES AVAILABLE FOR MODIFICATION OF THE PROPOSED FINAL JUDGMENT

The United States and the Defendants have stipulated that the proposed Final Judgment may be entered by this Court after compliance with the provisions of the APPA, provided that the United States has not withdrawn its consent. The APPA conditions entry of the decree upon this Court's determination that the proposed Final Judgment is in the public interest.

The APPA provides a period of at least sixty (60) days preceding the effective date of the proposed Final Judgment within which any person may submit to the United States written comments regarding the proposed Final Judgment. Any person who wishes to comment should do so within sixty (60) days of the date of publication of this Competitive Impact Statement in the Federal Register, or within sixty (60) days of the first date of publication in a newspaper of the summary of this Competitive Impact Statement, whichever is later. All comments received during this period will be considered by the United States Department of Justice, which remains free to withdraw its consent to the proposed Final Judgment at any time prior to the Court's entry of judgment. The comments and the response of the United States will be filed with this Court. In addition, comments will be posted on the U.S. Department of Justice, Antitrust Division's

internet website and, under certain circumstances, published in the Federal Register. Written comments should be submitted to:

Maribeth Petrizzi
Special Attorney, United States
c/o Federal Trade Commission
Bureau of Competition, Compliance Division, GAO-5T57
Org Code 1031, GAO-5K21
600 Pennsylvania Avenue, NW
Washington, DC 20580
Email: bccompliance@ftc.gov

The proposed Final Judgment provides that this Court retains jurisdiction over this action, and the parties may apply to this Court for any order necessary or appropriate for the modification, interpretation, or enforcement of the Final Judgment.

VI. ALTERNATIVES TO THE PROPOSED FINAL JUDGMENT

As an alternative to the proposed Final Judgment, the United States considered a full trial on the merits against the Defendants. The United States is satisfied, however, that the relief required by the proposed Final Judgment will remedy the violation alleged in the Complaint and deter violations by similarly situated entities in the future. Thus, the proposed Final Judgment achieves all or substantially all of the relief the United States would have obtained through litigation but avoids the time, expense, and uncertainty of a full trial on the merits.

VII. STANDARD OF REVIEW UNDER THE APPA FOR THE PROPOSED FINAL JUDGMENT

Under the Clayton Act and APPA, proposed Final Judgments, or "consent decrees," in antitrust cases brought by the United States are subject to a sixty (60) day comment period, after which the court shall determine whether entry of the proposed Final Judgment is "in the public interest." 15 U.S.C. § 16(e)(1). In making that determination, the court, in accordance with the statute as amended in 2004, is required to consider:

> (A) the competitive impact of such judgment, including termination of alleged violations, provisions for enforcement and modification, duration of relief sought, anticipated effects of alternative remedies actually considered, whether its terms are ambiguous, and any other competitive considerations bearing upon the adequacy of such judgment that the court deems necessary to a determination of whether the consent judgment is in the public interest; and
>
> (B) the impact of entry of such judgment upon competition in the relevant market or markets, upon the public generally and individuals alleging specific injury from the violations set forth in the complaint including consideration of the public benefit, if any, to be derived from a determination of the issues at trial.

Id. § 16(e)(1)(A) & (B). In considering these statutory factors, the court's inquiry is necessarily a limited one, as the government is entitled to "broad discretion to settle with the defendant within the reaches of the public interest." *United States v. Microsoft Corp.*, 56 F.3d 1448, 1461 (D.C. Cir. 1995); *United States v. U.S. Airways Group, Inc.*, 38 F. Supp. 3d 69, 75 (D.D.C. 2014) (noting the government has broad discretion of the adequacy of the relief at issue); *United States v. InBev N.V./S.A.*, No. 08-1965 (JR), 2009-2 Trade Cas. (CCH) ¶ 76,736, 2009 U.S. Dist. LEXIS 84787, at *3 (D.D.C. Aug. 11, 2009) (noting that the court's review of a consent judgment is limited and only inquires "into whether the government's determination that the proposed remedies will cure the antitrust violations alleged in the complaint was reasonable, and whether the mechanism to enforce the final judgment are clear and manageable.").

As the United States Court of Appeals for the District of Columbia Circuit has held, under the APPA a court considers, among other things, the relationship between the remedy secured and the specific allegations in the government's Complaint, whether the proposed Final Judgment is sufficiently clear, whether its enforcement mechanisms are sufficient, and whether it may positively harm third parties. *See Microsoft*, 56 F.3d at 1458–62. With respect to the adequacy of the relief secured by the proposed Final Judgment, a court may not "make de novo

determination of facts and issues." *United States v. W. Elec. Co.*, 993 F.2d 1572, 1577 (D.C. Cir. 1993) (quotation marks omitted); *see also Microsoft*, 56 F.3d at 1460–62; *United States v. Alcoa, Inc.*, 152 F. Supp. 2d 37, 40 (D.D.C. 2001); *United States v. Enova Corp.*, 107 F. Supp. 2d 10, 16 (D.D.C. 2000); *InBev*, 2009 U.S. Dist. LEXIS 84787, at *3.

Instead, "[t]he balancing of competing social and political interests affected by a proposed antitrust decree must be left, in the first instance, to the discretion of the Attorney General." *W. Elec. Co.*, 993 F.2d at 1577 (quotation marks omitted). "The court should also bear in mind the *flexibility* of the public interest inquiry: the court's function is not to determine whether the resulting array of rights and liabilities is the one that will *best* serve society, but only to confirm that the resulting settlement is within the *reaches* of the public interest." *Microsoft*, 56 F.3d at 1460 (quotation marks omitted); *see also United States v. Deutsche Telekom AG*, No. 19-2232 (TJK), 2020 WL 1873555, at *7 (D.D.C. Apr. 14, 2020). More demanding requirements would "have enormous practical consequences for the government's ability to negotiate future settlements," contrary to congressional intent. *Microsoft*, 56 F.3d at 1456. "The Tunney Act was not intended to create a disincentive to the use of the consent decree." *Id.*

The United States' predictions about the efficacy of the remedy are to be afforded deference by the Court. *See, e.g.*, *Microsoft*, 56 F.3d at 1461 (recognizing courts should give "due respect to the Justice Department's . . . view of the nature of its case"); *United States v. Iron Mountain, Inc.*, 217 F. Supp. 3d 146, 152–53 (D.D.C. 2016) ("In evaluating objections to settlement agreements under the Tunney Act, a court must be mindful that [t]he government need not prove that the settlements will perfectly remedy the alleged antitrust harms[;] it need only provide a factual basis for concluding that the settlements are reasonably adequate remedies

for the alleged harms." (internal citations omitted)); *United States v. Republic Servs., Inc.*, 723 F. Supp. 2d 157, 160 (D.D.C. 2010) (noting "the deferential review to which the government's proposed remedy is accorded"); *United States v. Archer-Daniels-Midland Co.*, 272 F. Supp. 2d 1, 6 (D.D.C. 2003) ("A district court must accord due respect to the government's prediction as to the effect of proposed remedies, its perception of the market structure, and its view of the nature of the case."). The ultimate question is whether "the remedies [obtained by the Final Judgment are] so inconsonant with the allegations charged as to fall outside of the 'reaches of the public interest.'" *Microsoft*, 56 F.3d at 1461 (*quoting W. Elec. Co*., 900 F.2d at 309).

Moreover, the court's role under the APPA is limited to reviewing the remedy in relationship to the violations that the United States has alleged in its Complaint and does not authorize the court to "construct [its] own hypothetical case and then evaluate the decree against that case." *Microsoft*, 56 F.3d at 1459; *see also U.S. Airways*, 38 F. Supp. 3d at 75 (noting that the court must simply determine whether there is a factual foundation for the government's decisions such that its conclusions regarding the proposed settlements are reasonable); *InBev*, 2009 U.S. Dist. LEXIS 84787, at *20 (concluding that "the 'public interest' is not to be measured by comparing the violations alleged in the complaint against those the court believes could have, or even should have, been alleged"). Because the "court's authority to review the decree depends entirely on the government's exercising its prosecutorial discretion by bringing a case in the first place," it follows that "the court is only authorized to review the decree itself," and not to "effectively redraft the complaint" to inquire into other matters that the United States did not pursue. *Microsoft*, 56 F.3d at 1459–60. As this Court confirmed in *United States v. SBC Communications, Inc.*, 489 F. Supp. 2d 1, 15 (D.D.C. 2007) courts "cannot look beyond the

complaint in making the public interest determination unless the complaint is drafted so narrowly as to make a mockery of judicial power."

In its 2004 amendments to the APPA, Congress made clear its intent to preserve the practical benefits of using judgments proposed by the United States in antitrust enforcement, adding the unambiguous instruction that "[n]othing in this section shall be construed to require the court to conduct an evidentiary hearing or to require the court to permit anyone to intervene." 15 U.S.C. § 16(e)(2); *see also U.S. Airways*, 38 F. Supp. 3d at 76 (indicating that a court is not required to hold an evidentiary hearing or to permit intervenors as part of its review under the Tunney Act). This language explicitly wrote into the statute what Congress intended when it enacted the Tunney Act in 1974. As Senator Tunney explained: "The court is nowhere compelled to go to trial or to engage in extended proceedings which might have the effect of vitiating the benefits of prompt and less costly settlement through the consent decree process." 119 Cong. Rec. 24,598 (1973) (statement of Sen. Tunney). "A court can make its public interest determination based on the competitive impact statement and response to public comments alone." *U.S. Airways*, 38 F. Supp. 3d at 76 (citing *Enova Corp.*, 107 F. Supp. 2d at 17).

VIII. DETERMINATIVE DOCUMENTS

There are no determinative materials or documents within the meaning of the APPA that were considered by the United States in formulating the proposed Final Judgment.

Date: July 13, 2026

Respectfully Submitted,

/s/ Jennifer Lee
Jennifer Lee
Special Attorney
U.S. Department of Justice

Antitrust Division
c/o Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, D.C. 20580
Phone: (202) 326-2246
Email: jlee@ftc.gov