UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN

MARK NOWACKI, as Legal Guardian and Conservator for DANIEL NOWACKI, and KATHLEEN P. NOWACKI, Plaintiffs, v. GILEAD SCIENCES, INC. and ST. JOSEPH MERCY CHELSEA, INC. d/b/a ST. JOSEPH MERCY CHELSEA, Defendants.	Civil Action No. _____ (Removal from the Circuit Court for the County of Washtenaw, Michigan)

DEFENDANT GILEAD SCIENCES, INC.'S NOTICE OF REMOVAL

Defendant Gilead Sciences, Inc. ("Gilead") hereby files this Notice of Removal of the above-captioned action from the Circuit Court for the County of Washtenaw, Michigan to the United States District Court for the Eastern District of Michigan. This Notice of Removal is filed pursuant to 28 U.S.C. §§ 1331, 1367, 1441, and 1446 on the basis of the following facts, which show that this action may be properly removed to this Court:

I. THE STATE COURT ACTION

1. On December 28, 2022, Plaintiffs Mark Nowacki, as Legal Guardian

and Conservator for Daniel Nowacki, and Kathleen P. Nowacki ("Plaintiffs") filed a civil action in the Circuit Court for the County of Washtenaw, Michigan entitled *Mark Nowacki, as Legal Guardian and Conservator for Daniel Nowacki, and Kathleen P. Nowacki v. Gilead Sciences, Inc., and St. Joseph Mercy Chelsea, Inc. d/b/a St. Joseph Mercy Chelsea*, Case No. 22-001761-NP (the "State Court Action").

2. Pursuant to 28 U.S.C. § 1446(a), a true and correct copy of all process and pleadings served on Gilead in the State Court Action is attached hereto as **Exhibit A**.

3. Pursuant to 28 U.S.C. § 1446(a), a true and correct copy of all process and pleadings served on St. Joseph Mercy in the State Court Action is attached hereto as **Exhibit B**.

4. Plaintiffs' Complaint ("Complaint") alleges that Daniel Nowacki suffered injuries after receiving remdesivir to treat his COVID-19. **Ex. A**, Compl. ¶¶ 9–14. Remdesivir is a prescription drug manufactured by Gilead and approved by the U.S. Food and Drug Administration to treat COVID-19. **Ex. A**, Compl. ¶¶ 26, 28.

5. The Complaint alleges that Mr. Nowacki received remdesivir that was subject to a recall due to the possible presence of glass particles which caused him to suffer two strokes, undergo a leg amputation, and become bedridden. **Ex. A**, Compl. ¶¶ 15–25.

6. The Complaint asserts causes of action against Gilead for Breach of Implied Warranty, Breach of Express Warranty, Negligence, Gross Negligence, Intentional Misrepresentation, and Loss of Consortium. It also asserts causes of action against St. Joseph Mercy Chelsea, Inc. d/b/a St. Joseph Mercy Chelsea ("St. Joseph Mercy"), the hospital where Mr. Nowacki allegedly received treatment for COVID-19 and was administered remdesivir, for Negligence, Gross Negligence, and Loss of Consortium. **Ex. A**, Compl. ¶¶ 40–82.

7. The Complaint seeks monetary damages. **Ex. A**, Compl. ¶¶ 48, 56, 60, 66, 73, 76, 80, 82.

II. PROCEDURAL REQUIREMENTS

8. Gilead was served with process on January 3, 2023. Gilead has filed this Notice of Removal within thirty days of the date of service. *See* 28 U.S.C. § 1446(b)(2)(B).

9. Promptly after filing this Notice of Removal, Gilead will serve this Notice of Removal upon Plaintiffs and file a copy of this Notice of Removal with the Clerk of the Circuit Court for Washtenaw County, Michigan. *See id.* § 1446(d).

10. The Circuit Court for Washtenaw County, Michigan, where the Complaint was filed, is a state court within the Eastern District of Michigan. Removal to this Court is therefore proper. *See id.* §§ 102(a), 1391(b), 1441(a), 1446(a).

11. Gilead has conferred with counsel for St. Joseph Mercy, and St. Joseph Mercy consents to removal. *See id.* § 1446(b)(2)(A); **Exhibit C**, Consent by St. Joseph Mercy.

12. Nothing in this Notice of Removal is or should be interpreted as a waiver or relinquishment of Gilead's right to assert any defenses or affirmative matters, including without limitation the defenses of (1) lack of personal jurisdiction; (2) improper venue; (3) insufficiency of process; (4) insufficiency of service of process; (5) failure to state a claim; or (6) any other procedural or substantive defense available under federal or state law.

III. THE PREP ACT

13. The Public Readiness and Preparedness Act, 42 U.S.C. §§ 247d-6d, 247d-6e ("PREP Act"), affords legal protections to individuals and entities involved in the response to a nationwide public health emergency such as the COVID-19 pandemic.

14. The PREP Act authorizes the Secretary of Health and Human Services ("HHS") to issue a declaration granting "covered person[s]" "immun[ity] from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure" during a public health emergency. 42 U.S.C. § 247d-6d(a)(1).

15. This immunity extends to "any claim" with "a causal relationship" to a covered countermeasure's "design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use." *Id.* § 247d-6d(a)(2)(b). And this immunity applies to claims for "any type of loss, including—(i) death; (ii) physical, mental, or emotional injury, illness, disability, or condition; or (iii) fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring." *Id*. § 247d-6d(a)(2)(A).

16. "Covered person[s]" under the PREP Act include "manufacturer[s]," "distributor[s]," and "program planners" of countermeasures, as well as "qualified person[s] who prescribed, administered, or dispensed . . . countermeasure[s]." *Id.* § 247d-6d(i)(2).

17. "Covered countermeasures" under the PREP Act include "qualified pandemic or epidemic product[s]," such as diagnostics, treatments, or protective gear, as designated by a declaration of the HHS Secretary. *Id.* § 247d-6d(i)(7).

18. The "sole exception" to the PREP Act's grant of immunity is an "exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct" by the covered person. *Id.* § 247d-6d(d)(1). "Willful misconduct" means "an act or omission that is taken—(i) intentionally to achieve a wrongful purpose; (ii) knowingly without legal or

factual justification; and (iii) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit." *Id.* § 247d-6d(c)(1). This exclusive federal cause of action must be brought in the United States District Court for the District of Columbia. *Id.* § 247d-6d(e)(1).

19. The PREP Act also creates an "exclusive" federal administrative remedy for claims to which the Act's immunity extends, establishing a "Covered Countermeasure Process Fund" designed to provide "timely, uniform, and adequate compensation" via a no-fault claims process. *Id.* §§ 247d-6e(a), (d).

20. Moreover, the PREP Act expressly preempts state law, providing that "no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that is different from, or in conflict with, any requirement applicable under this section [] and relates to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, or any other aspect of safety or efficacy" of such covered countermeasure "or to any matter included in a requirement applicable to the covered countermeasure under," among other things, "the Federal Food, Drug, and Cosmetic Act." *Id.* § 247d-6d(b)(8).

21. Effective February 4, 2020, the HHS Secretary issued a PREP Act declaration granting immunity to, *inter alia*, entities that manufacture and administer

drugs used to treat COVID-19. Declaration Under the PREP Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15,198, 15,201, 15,202 (Mar. 17, 2020). Consistent with the Act, the declaration defined "covered persons" to include "manufacturers" and "program planners" of covered countermeasures, as well as "qualified persons" who prescribed, administered, or dispensed such countermeasures. *Id.* at 15,201. The declaration also designated "any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19" as a "covered countermeasure[]." *Id.* at 15,202.

22. The HHS Secretary has since amended the declaration a number of times, most recently in January 2022, to clarify and expand the scope of covered persons and countermeasures. *See* Tenth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 87 Fed. Reg. 982 (Jan. 7, 2022). This most recent amendment generally extended PREP Act immunity related to the administration and use of COVID-19 countermeasures through October 1, 2024. *See id.* at 988.

III. COMPLETE PREEMPTION AND FEDERAL QUESTION JURISDICTION

23. This case may be removed under 28 U.S.C. § 1441(a) because this Court has original subject-matter jurisdiction. Pursuant to the doctrine of complete

preemption, Plaintiffs' claims against Gilead arise under federal law within the meaning of 28 U.S.C. § 1331.

24. Complete preemption recognizes that "Congress may so completely preempt a particular area" of law that any state-law claims within this defined area become "necessarily federal in nature." *Metro Life Ins. Co. v. Taylor*, 481 U.S. 58, 63–64 (1987). "Once an area of state law has been completely preempted, any claim purportedly based on that pre-empted state law is considered, from its inception, a federal claim, and therefore arises under federal law." *Caterpillar Inc. v. Williams*, 482 U.S. 386, 393 (1987). Such a claim is, accordingly, removable to federal court. *Beneficial Nat'l Bank v. Anderson*, 539 U.S. 1, 8 (2003) ("When the federal statute completely pre-empts the state-law cause of action, a claim which comes within the scope of that cause of action, even if pleaded in terms of state law, is in reality based on federal law. This claim is then removable . . . .").

25. "The congressional intent necessary to confer removal jurisdiction upon the federal district courts through complete preemption is expressed through the creation of a parallel federal cause of action that would 'convert' a state cause of action into the federal action for purposes of the well-pleaded complaint rule." *Hudak v. Elmcroft of Sagamore Hills*, --- F.4th ---, 2023 WL 352711, at *5 (6th Cir. Jan. 23, 2023) (internal quotation marks and citation omitted). Thus, to determine whether a federal statute completely preempts a state-law claim, courts ask whether

(i) the federal statute creates an "exclusive cause of action," and (ii) the claim "comes within the scope of that cause of action." *Beneficial Nat'l Bank*, 539 U.S. at 8; *see also Aetna Health Inc. v. Davila*, 542 U.S. 200, 208–09 (2004) (analyzing "the clear congressional intent to make the ERISA remedy exclusive" and observing that "a claim which comes within the scope of that" exclusive remedy is completely preempted); *Hudak*, 2023 WL 352711, at *5–7 (analyzing whether claims pleaded under state law fell within the scope of the PREP Act's exclusive federal cause of action).

26. Federal courts have identified several complete preemption statutes. *See, e.g.*, *Beneficial Nat'l Bank*, 539 U.S. at 1 (National Bank Act); *Avco Corp. v. Aero Lodge No. 735, Int'l Ass'n of Machinists & Aerospace Workers*, 390 U.S. 557 (1968) (Labor Management Relations Act); *Metro Life*, 481 U.S. 58 (ERISA); *Ritchie v. Williams*, 395 F.3d 283 (6th Cir. 2005) (Copyright Act); *Gibson v. Am. Bankers Ins. Co.*, 289 F.3d 943 (6th Cir. 2002) (National Flood Insurance Act); *In re WTC Disaster Site*, 414 F.3d 352 (2d Cir. 2005) (Air Transportation Safety and System Stabilization Act).

27. In a recent decision, the Sixth Circuit reserved the question of "whether [the PREP Act] is completely preemptive." *Hudak*, 2023 WL 352711, at *5; *see also id.* at *7 n.3 ("We express no view as to whether § 247d-6d(d)(1) completely

preempts state-law claims that fall within its scope."); *id*. at *5 (noting that other circuits are divided on this question).

28. In *Hudak*, a nursing home removed to federal court, based on complete preemption under the PREP Act, an action alleging that a resident died of COVID-19 due to the nursing home's failure to administer sufficient precautions and care. The district court remanded the action, and the Sixth Circuit affirmed. The Sixth Circuit held that the plaintiff's "claims do not fall within the scope of the [PREP Act's] federal cause of action for two reasons." *Id.*

29. First, the Sixth Circuit found that the complaint was "devoid of allegations" that the defendant engaged in willful misconduct. Discounting the complaint's labels and focusing on its "gravamen," the Sixth Circuit found that the conduct alleged did not sound in willful misconduct. *Id*. Instead, the complaint alleged that the decedent's death was caused by the nursing home's failure "to ensure that its employees wore masks, to assess whether it could care for [plaintiff] after he became sick, or to transfer him to another facility that could provide the appropriate care." *Id*. "Because Hudak does not allege willful misconduct within the meaning of the PREP Act, the Act does not provide her with a federal cause of action and her claims are not completely preempted." *Id*. at *6.

30. Second, the Sixth Circuit held that the plaintiff's complaint did not fall within the scope of the PREP Act *at all* because the plaintiff's allegations did not

relate to the nursing home's "administration or use" of a COVID-19 countermeasure, as the Act requires, but rather its *failure* to administer and use such countermeasures. *Id.* at *7; *see id*. at *6 ("Nowhere in the complaint does Hudak allege that 'the administration to or use by [the decedent] of a' COVID-19 countermeasure caused his illness or death.") (quoting 42 U.S.C. § 247d-6d(a)(2)(B)).

31. This action is different in both respects. First, unlike the complaint in *Hudak*, the Complaint here contains numerous allegations that sound in willful misconduct, *i.e.*, conduct taken "(i) intentionally to achieve a wrongful purpose; (ii) knowingly without legal or factual justification; and (iii) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit." 42 U.S.C. § 247d-6d(c)(1); *see, e.g.*, **Ex. A**, Compl. ¶¶ 31 ("Gilead did not disclose and/or misrepresented to the FDA about the possibility of glass particles (foreign body) being present in the drug composition and/or some batches thereof which could cause serious adverse events such as, [sic] stroke and/or death."), 53 ("Gilead knew, or should have known, at the time Remdesivir drug containing glass particles (foreign body) left its control that it was defective and dangerous and there was a substantial likelihood that the glass particles would cause serious injuries which form the basis for this action."), 59 (same), 63 (same), 64 ("Gilead introduced Remdesivir drug containing glass particles (foreign body) into

the stream of commerce knowing fully well that the glass particles could cause serious injuries such as, [sic] stroke and/or even death.").[1]

32. And second, unlike the plaintiff in *Hudak*, Plaintiffs allege injury resulting from the administration and use of a COVID-19 countermeasure, not the failure to use COVID-19 countermeasures. *See* **Ex. A**, Compl. ¶¶ 24–25 ("Dan had received Remdesivir that contained glass particles . . . As a result of these glass particles, Dan has suffered two strokes and has had a leg amputated and is left bedridden for rest [sic] of his life thereby requiring 24/7 care."). The present action falls within the central core of the PREP Act and is fundamentally distinct from *Hudak*.

33. Here, the PREP Act completely preempts Plaintiffs' claims against Gilead.

34. The Act creates an "exclusive cause of action" for death or grave physical injury caused by a covered person's willful misconduct. *Beneficial Nat'l Bank*, 539 U.S. at 8; *see* 42 U.S.C. § 247d-6d(d)(1).

[1] To be clear, Gilead denies that it engaged in willful misconduct, but whether this Court has subject-matter jurisdiction turns on whether Plaintiffs' allegations fall within the scope of the PREP Act's exclusive federal cause of action, not whether Plaintiffs have a meritorious claim. *See Bell v. Hood*, 327 U.S. 678, 682-83 (1946) (whether a federal cause of action states a claim upon which relief can be granted "must be decided after, and not before, the court has assumed jurisdiction over the controversy"; jurisdiction exists unless the federal claim is "immaterial" or "wholly insubstantial and frivolous").

35. And Plaintiffs' claims against Gilead "come[] within the scope of that cause of action." *Beneficial Nat'l Bank*, 539 U.S. at 8. Plaintiffs allege that a "covered person" took actions akin to "willful misconduct" with respect to a "covered countermeasure." Remdesivir, a drug approved to treat COVID-19, is a "covered countermeasure." 85 Fed. Reg. at 15,202; 42 U.S.C. § 247d-6d(i)(1), *see* **Ex. A**, Compl. ¶¶ 26–28. Gilead, its "manufacturer," is a covered person. 42 U.S.C. § 247d-6d(i)(2); *see* 85 Fed. Reg. at 15,201–02. And, as noted above, the Complaint makes multiple allegations implying that Gilead acted "intentionally to achieve a wrongful purpose; (ii) knowingly without legal or factual justification; and (iii) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit." 42 U.S.C. § 247d-6d(c)(1), *see supra* ¶ 31.

36. The PREP Act therefore "provide[s] the exclusive cause of action for the claim[s] asserted" against Gilead and "completely preempt[s]" those claims. *Hudak*, 2023 WL 352711, at *7.

37. The United States agrees that the PREP Act gives rise to complete preemption. *See* Advisory Opinion No. 21-01 at 2 (HHS General Counsel Jan. 8, 2021) ("The PREP Act Is A 'Complete Preemption' Statute"); DOJ Statement of Interest, *Bolton v. Gallatin Ctr. for Rehab. & Healing, LLC*, No. 20-cv-00683 (M.D. Tenn. Jan. 19, 2021), ECF No. 35-1.

38. Because the PREP Act completely preempts Plaintiffs' claims against Gilead, those claims arise under federal law and give rise to federal question jurisdiction. Removal is therefore proper pursuant to 28 U.S.C. §§ 1331 and 1441(a).

IV. SUPPLEMENTAL JURISDICTION

39. Pursuant to 28 U.S.C. § 1367(a), supplemental jurisdiction exists over Plaintiffs' claims against St. Joseph Mercy.

40. These claims—which allege that St. Joseph Mercy breached a duty to expeditiously warn Mr. Nowacki that he had received remdesivir doses subject to a recall—"are so related to the claims" against Gilead "that they form part of the same case or controversy under Article III of the United States Constitution." 28 U.S.C. § 1367(a); *see also Hucul Advert., LLC v. Charter Twp. of Gaines*, 748 F.3d 273, 280 (6th Cir. 2014) ("Claims form part of the same case or controversy when they derive from a common nucleus of operative facts."); *Blakely v. U.S.*, 276 F.3d 853, 861 (6th Cir. 2002) (explaining that "if there is some basis for original jurisdiction, the default assumption is that the court will exercise supplemental jurisdiction over all related claims" (internal quotation marks and citation omitted)).

VI. CONCLUSION

41. For all the reasons stated, this action is removable to this Court pursuant to 28 U.S.C. §§ 1441(a) and 1446, and this Court may exercise jurisdiction over this

entire matter pursuant to 28 U.S.C. § 1331 and 1367.

Wherefore, Gilead gives notice that the action entitled *Mark Nowacki, as Legal Guardian and Conservator for Daniel Nowacki, and Kathleen P. Nowacki v. Gilead Sciences, Inc., and St. Joseph Mercy Chelsea, Inc. d/b/a St. Joseph Mercy Chelsea*, Case No. 22-001761-NP, currently pending in the Circuit Court for Washtenaw County, Michigan, is removed to the United States District Court for the Eastern District of Michigan and requests that this Court retain jurisdiction over all further proceedings in this matter.

Respectfully submitted this 2nd day of February 2023.

Respectfully submitted,
DYKEMA GOSSETT PLLC
/s/ *Bonnie Mayfield*
Bonnie Mayfield (P40275)
Krista L. Lenart (P59601)
Attorneys for Gilead
39577 Woodward Ave., Suite 300
Bloomfield Hills, MI 48304
(248) 203-0851; (855) 245-0194 (fax)
bmayfield@dykema.com
klenart@dykema.com

CERTIFICATE OF SERVICE

Bonnie Mayfield of Dykema Gossett PLLC, certifies that on February 2, 2023, she caused to be served copies of the attached *Notice of Removal* along with this *Certificate of Service*, via U.S. mail with prepaid, first class postage affixed, to counsel of record at the following addresses:

JOHNSON LAW, PLC Vernon R. Johnson Kanwarpreet Singh Khahra Buhl Building 535 Griswold Street, Ste. 2632 Detroit, MI 48226	TANOURY NAUTS MCKINNEY & GARBARINO PLLC David R. Nauts 38777 6 Mile Suite 101 Livonia, MI 48152-2660

/s/ *Bonnie Mayfield*

Bonnie Mayfield (P40275)
Krista L. Lenart (P59601)
DYKEMA GOSSETT PLLC
Attorneys for Gilead
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klenart@dykema.com

4891-2484-0782.1

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN

MARK NOWACKI, as Legal Guardian and Conservator for DANIEL NOWACKI, and KATHLEEN P. NOWACKI,

Plaintiffs,

v.

GILEAD SCIENCES, INC. and ST. JOSEPH MERCY CHELSEA, INC. d/b/a ST. JOSEPH MERCY CHELSEA,

Defendants.

Civil Action No. _____

(Removal from the Circuit Court for the County of Washtenaw, Michigan)

INDEX OF EXHIBITS TO
DEFENDANT GILEAD SCIENCES, INC.'S NOTICE OF REMOVAL

Exhibit A - All Process and Pleadings Served Upon Gilead Sciences, Inc.

Exhibit B - All Process and Pleadings Served Upon St. Joseph Mercy Chelsea

Exhibit C - Consent to Removal

Exhibit A

Wolters Kluwer

CT Corporation
Service of Process Notification
01/05/2023
CT Log Number 542966832

Service of Process Transmittal Summary

TO: David Meresman
Gilead Sciences, Inc.
333 Lakeside Dr
Foster City, CA 94404-1147

RE: **Process Served in Michigan**

FOR: Gilead Sciences, Inc. (Domestic State: DE)

ENCLOSED ARE COPIES OF LEGAL PROCESS RECEIVED BY THE STATUTORY AGENT OF THE ABOVE COMPANY AS FOLLOWS:

TITLE OF ACTION:	MARK NOWACKI, as Legal Guardian and Conservator for DANIEL NOWACKI, and KATHLEEN P. NOWACKI vs. GILEAD SCIENCES, INC.
CASE #:	22001761NP
PROCESS SERVED ON:	The Corporation Company, Plymouth, MI
DATE/METHOD OF SERVICE:	By Traceable Mail on 01/05/2023
JURISDICTION SERVED:	Michigan
ACTION ITEMS:	CT will retain the current log
	Image SOP
	Email Notification, David Meresman david.meresman@gilead.com
	Email Notification, Plato Mok Plato.Mok@gilead.com
	Email Notification, David Meresman david.meresman@gilead.com
	Email Notification, Keeley Wettan keeley.wettan@gilead.com
	Email Notification, Diana Gama diana.gama@gilead.com
	Email Notification, Jocelyn Delavega jocelyn.delavega@gilead.com
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	Email Notification, Katie Rice katharine.rice@gilead.com
	Email Notification, Rachel Gupte rachel.gupte@gilead.com
	Email Notification, Nell Clement nell.clement@gilead.com
REGISTERED AGENT CONTACT:	The Corporation Company 40600 Ann Arbor Road E Suite 201 Plymouth, MI 48170 866-665-5799 SouthTeam2@wolterskluwer.com

The information contained in this Transmittal is provided by CT for quick reference only. It does not constitute a legal opinion, and should not otherwise be relied on, as to the nature of action, the amount of damages, the answer date, or any other information contained in the included documents. The recipient(s) of this form is responsible for reviewing and interpreting the

included documents and taking appropriate action, including consulting with its legal and other advisors as necessary. CT disclaims all liability for the information contained in this form, including for any omissions or inaccuracies that may be contained therein.

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Detroit, MI 48226

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Ken S. Khahra, Esq.
Johnson Law, PLC
535 Griswold St Ste 2600
Detroit MI 48226-3687

SHIP TO: Gilead Sciences, Inc.
Res Agent: CT Corporation System
40600 Ann Arbor Rd E Ste 201
Plymouth MI 48170-4675

USPS CERTIFIED MAIL™
9414 7118 9956 2404 3456 07

JOHNSON LAW, PLC

CERTIFIED MAIL
GILEAD SCIENCES, INC.
Resident Agent: CT Corporation System
40600 Ann Arbor Rd, E, Ste 201
Plymouth, MI 48170

Ven
JOHNSON LAW, PLC

December 30, 2022

VIA PERSONAL SERVICE and CERTIFIED MAIL
GILEAD SCIENCES, INC.
Resident Agent: CT Corporation System
40600 Ann Arbor Rd, E, Ste 201
Plymouth, MI 48170

Re: Mark Nowacki, as Legal Guardian and Conservator for Daniel Nowacki, et al. v Gilead Sciences, Inc.
Washtenaw County Circuit Court Case No. 22-001761-NP

Dear Mr. Sir/Madam:

We represent the plaintiff in the above-entitled action. Enclosed please find:

1. Summons for Defendant Gilead Sciences, Inc.; and

2. Complaint and Jury Demand.

Please provide these documents to your insurance carrier and conduct yourself accordingly.

Thank you for your attention in this regard.

Yours very truly,

JOHNSON LAW, PLC

Khahra

Ken S. Khahra

KSK/cts
Enclosures

Approved, SCAO

Original - Court
1st copy - Defendant

2nd copy - Plaintiff
3rd copy - Return

STATE OF MICHIGAN 22nd JUDICIAL DISTRICT JUDICIAL CIRCUIT COUNTY PROBATE	SUMMONS	CASE NO. 22- -NP 22-001761-NP

Court address
101 E Huron St., Ann Arbor, MI 48104

Court telephone no.
734-222-3001

Plaintiff's name(s), address(es), and telephone no(s).		Defendant's name(s), address(es), and telephone no(s).
MARK NOWACKI, as Legal Guardian and Conservator for DANIEL NOWACKI, and KATHLEEN NOWACKI,	v	GILEAD SCIENCES, INC. Resident Agent: The Corporation Company 40600 Ann Arbor Road East, Ste 201 Plymouth, MI 48170
Plaintiff's attorney, bar no., address, and telephone no. KEN S. KHAHRA (P80253) JOHNSON LAW, PLC 535 Griswold St., Ste 2600 Detroit, MI 48226 313-324-8301		

Instructions: Check the items below that apply to you and provide any required information. Submit this form to the court clerk along with your complaint and, if necessary, a case inventory addendum (form MC 21). The summons section will be completed by the court clerk.

Domestic Relations Case

☐ There are no pending or resolved cases within the jurisdiction of the family division of the circuit court involving the family or family members of the person(s) who are the subject of the complaint.

☐ There is one or more pending or resolved cases within the jurisdiction of the family division of the circuit court involving the family or family members of the person(s) who are the subject of the complaint. I have separately filed a completed confidential case inventory (form MC 21) listing those cases.

☐ It is unknown if there are pending or resolved cases within the jurisdiction of the family division of the circuit court involving the family or family members of the person(s) who are the subject of the complaint.

Civil Case

☐ This is a business case in which all or part of the action includes a business or commercial dispute under MCL 600.8035.

☐ MDHHS and a contracted health plan may have a right to recover expenses in this case. I certify that notice and a copy of the complaint will be provided to MDHHS and (if applicable) the contracted health plan in accordance with MCL 400.106(4).

☑ There is no other pending or resolved civil action arising out of the same transaction or occurrence as alleged in the complaint.

☐ A civil action between these parties or other parties arising out of the transaction or occurrence alleged in the complaint has been previously filed in ☐ this court, ☐ _____ Court, where it was given case number _____ and assigned to Judge _____.

The action ☐ remains ☐ is no longer pending.

Summons section completed by court clerk. **SUMMONS**

NOTICE TO THE DEFENDANT: In the name of the people of the State of Michigan you are notified:

1. You are being sued.
2. **YOU HAVE 21 DAYS** after receiving this summons and a copy of the complaint to **file a written answer with the court** and serve a copy on the other party **or take other lawful action with the court** (28 days if you were served by mail or you were served outside this state).
3. If you do not answer or take other action within the time allowed, judgment may be entered against you for the relief demanded in the complaint.
4. If you require special accommodations to use the court because of a disability or if you require a foreign language interpreter to help you fully participate in court proceedings, please contact the court immediately to make arrangements.

Issue date	Expiration date*	Court clerk
	03-29-2023	/s/ Kim Plumb December 29, 2022

*This summons is invalid unless served on or before its expiration date. This document must be sealed by the seal of the court.

SUMMONS
Case No. 22- -NP

PROOF OF SERVICE

TO PROCESS SERVER: You are to serve the summons and complaint not later than 91 days from the date of filing or the date of expiration on the order for second summons. You must make and file your return with the court clerk. If you are unable to complete service you must return this original and all copies to the court clerk.

CERTIFICATE / AFFIDAVIT OF SERVICE / NONSERVICE

☐ **OFFICER CERTIFICATE**
I certify that I am a sheriff, deputy sheriff, bailiff, appointed court officer, or attorney for a party (MCR 2.104[A][2]), and that: (notarization not required)

OR

☐ **AFFIDAVIT OF PROCESS SERVER**
Being first duly sworn, I state that I am a legally competent adult, and I am not a party or an officer of a corporate party (MCR 2.103[A]), and that: (notarization required)

☐ I served personally a copy of the summons and complaint,
☐ I served by registered or certified mail (copy of return receipt attached) a copy of the summons and complaint,

together with _____
List all documents served with the summons and complaint

_____ on the defendant(s):

Defendant's name	Complete address(es) of service	Day, date, time

☐ I have personally attempted to serve the summons and complaint, together with any attachments, on the following defendant(s) and have been unable to complete service.

Defendant's name	Complete address(es) of service	Day, date, time

I declare under the penalties of perjury that this proof of service has been examined by me and that its contents are true to the best of my information, knowledge, and belief.

Service fee	Miles traveled	Fee	
$		$	
Incorrect address fee	Miles traveled	Fee	TOTAL FEE
$		$	$

_____
Signature

_____
Name (type or print)

_____
Title

Subscribed and sworn to before me on _____ (Date), _____ County, Michigan.

My commission expires: _____ (Date) Signature: _____ (Deputy court clerk/Notary public)

Notary public, State of Michigan, County of _____

ACKNOWLEDGMENT OF SERVICE

I acknowledge that I have received service of the summons and complaint, together with _____ (Attachments)

_____ on _____ (Day, date, time)

_____ on behalf of _____.
Signature

STATE OF MICHIGAN

IN THE CIRCUIT COURT FOR THE COUNTY OF WASHTENAW

MARK NOWACKI, as Legal Guardian and Conservator
for DANIEL NOWACKI, and KATHLEEN P. NOWACKI,

Plaintiffs,

22-001761-NP

Case No.: 22- -NP
Hon. JUDGE CAROL KUHNKE

vs

GILEAD SCIENCES, INC., and
ST. JOSEPH MERCY CHELSEA, INC., *d/b/a*
ST. JOSEPH MERCY CHELSEA,

Defendants.
_____/

KANWARPREET S. KHAHRA (P80253)
VEN R. JOHNSON (P39219)
JOHNSON LAW, PLC
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kkhahra@venjohnsonlaw.com
vjohnson@venjohnsonlaw.com
_____/

The undersigned hereby certifies that there is no other pending or resolved civil action between the same parties arising out of the transaction or occurrence alleged in the complaint.

/s/ Kanwarpreet S. Khahra
Kanwarpreet S. Khahra

COMPLAINT AND DEMAND FOR JURY TRIAL

NOW COMES, the Plaintiffs, MARK NOWACKI, as Legal Guardian and Conservator for DANIEL NOWACKI, and KATHLEEN P. NOWACKI, by and through his attorneys, JOHNSON LAW, PLC, for his complaint and cause of action against Defendants, GILEAD SCIENCES INC., and ST. JOSEPH MERCY CHELSEA, INC., states the following:

1. The acts or omissions which form the basis for this complaint occurred in the County of Washtenaw, State of Michigan.

2. The amount in controversy is in excess of TWENTY-FIVE THOUSAND ($25,000) dollars exclusive of costs, interest, and attorney fee.

3. Venue is proper pursuant to MCL 600.1629.

4. At all times pertinent to the complaint, Plaintiff, MARK NOWACKI, as Legal Guardian and Conservator for DANIEL NOWACKI (hereinafter "Dan") was a resident of Onsted, County of Lenawee, State of Michigan.

5. At all times pertinent to the complaint, Plaintiff, KATHLEEN P. NOWACKI, was the lawfully wedded wife of DANIEL NOWACKI and resided with him in Michigan.

6. At all times pertinent to the complaint, Defendant, GILEAD SCIENCES INC., (hereinafter "GILEAD") was a domestic corporation incorporated under the laws of Delaware, doing continuous and systemic business in the State of Michigan. The resident agent for GILEAD in Michigan is: THE CORPORATION COMPANY, which is located at 40600 Ann Arbor Road East, Suite 201, Plymouth, Michigan.

7. At all times pertinent to the complaint, Defendant, ST. JOSEPH MERCY CHELSEA, INC., (hereinafter "St. Joseph Mercy hospital") was a domestic corporation incorporated under the laws of Michigan, doing continuous and systemic business in the State of Michigan. The resident agent of ST. JOSEPH MERCY is: THE CORPORATION COMPANY, which is located at 40600 Ann Arbor Road East, Suite 201, Plymouth, Michigan.

8. In paragraphs 9-20 as set forth below, the Plaintiffs makes reference to the statements contained in the medical records of various health care providers of DANIEL NOWACKI. The recitation of these factual statements should not be interpreted as an admission

by Plaintiffs as to the factual authenticity or truthfulness of these statements. The statements are set forth below to provide context as to the allegations as described below.

STATEMENT OF FACTS

9. On November 9, 2021, Daniel Nowacki (83) presented to St. Joseph Mercy hospital in Chelsea, MI, with complaints of fatigue for past three (3) days, cough, some shortness of breath, and decreased appetite.

10. That same day, Dan was diagnosed with COVID-19 and received monoclonal antibodies and was discharged home.

11. On November 10, 2021, Dan returned to the emergency department at St. Joseph Mercy via EMS because of worsening fatigue and shortness of breath. EMS noted that Dan was hypoxic with his SPO2 at 86% on room air.

12. A chest x-ray performed at the hospital revealed mild to moderate airspace disease throughout the bilateral lungs and possible trace of pleural effusion.

13. On November 10, 2021, Dan received IV Decadron and Remdesivir (also known as Veklury) to treat his hypoxia.

14. On November 11, 2021, Dan received another dose of IV Remdesivir.

15. After receiving Remdesivir, Dan's experienced a stroke which was confirmed by CTA Head/Neck on November 19, 2021, and showed, *inter alia*, a complete occlusion of the right internal carotid artery.

16. On November 20, 2021, Dan underwent an MRI Brain to rule out Dural Venous Thrombosis which revealed,

a. Moderate sized region of acute infarction involves right cerebral hemisphere, predominantly affecting mid-posterior right frontal and right parietal lobes. This region of restricted water diffusion is somewhat oriented in a linear parasagittal configuration which may indicate "watershed-type" ischemia.

b. Brain volume/intracranial atrophy compared to the Head CT on 11/18/2021.

c. More focal encephalomalacia involving right frontal lobe, probability due to prior infarction.

d. Scattered foci of T2 hyperintensity within cerebral hemispheric white matter and adjacent basal ganglia not associated with mass effect, contrast enhancement or restricted water diffusion probably due to subacute/chronic ischemia.

e. Absence of anticipated flow-void from upper cervical and proximal intracranial right internal carotid artery suggesting altered flow. The findings are consistent with previously diagnosed right internal carotid artery occlusion.

17. Dan was diagnosed with cerebral infarction due to vascular occlusion and discharged on November 24, 2021, to a skilled nursing facility.

18. Over the next several days, Dan started developing hematomas and reported swelling on his face, thighs, arms and was admitted to Henry Ford hospital. The cause of these hematomas and swelling remained a mystery to Dan's treating physicians.

19. On approximately December 14, 2021, Dan suffered another stroke in the posterior frontal, parietal, and occipital region which has left him bedridden.

20. On April 6, 2022, Mark Nowacki received a letter from St. Joseph Mercy hospital (Chelsea) confirming that Dan had received five doses of Remdesivir during his November 10, 2022, admission which were subject to Gilead nationwide recall of Remdesivir due to presence of foreign body – glass particles in the drug. **(Letter, Exhibit 1).**

21. The recall dated December 3, 2021, pertained to two lots (#2141001-1A and 2141002-1A) totaling approximately 55,000 vials of Remdesivir. **(Recall, Exhibit 2).** The recall was published on FDA website and contained the following risk statement:

> The administration of an injectable that contains glass particulates may result in local irritation or swelling in response to the foreign material. If the glass particulate reaches the blood vessels it can travel to various organs and block blood vessels in the heart, lungs,

> or brain which can cause stroke and even lead to death. To date, Gilead Sciences Inc., has not received any reports of adverse events related to this recall.

22. While Gilead indicated in the recall that it had not received any reports of adverse events, the company acknowledged in the recall notification that it had received a customer complaint, confirmed by company's investigation, which led to the discovery of glass particles.

23. The recall further stated that Gilead is notifying its distributors and customers via UPS next day air mail to hospital pharmacies and is facilitating the return of any remaining vials from the affected lots. Hospitals that have Veklury [Remdesivir] which is being recalled should stop using the affected lots and return the product vials per the instructions.

24. Unfortunately, neither Dan nor his family was made aware that Dan had received Remdesivir that contained glass particles (foreign body) which was responsible for causing his stroke until after a letter was received from St. Joseph Mercy on or about April 6, 2022. As such, Dan's subsequent treating physicians including staff at Henry Ford were unaware of this fact and could not appropriately deal with Dan's medical condition.

25. As a result of these glass particles, Dan has suffered two strokes and has had a leg amputated and is left bedridden for rest of his life thereby requiring 24/7 care.

REMDESIVIR [VEKLURY] BACKGROUND

26. Remdesivir was the first experimental drug to receive FDA approval for treatment against COVID-19 in certain patient population.

27. The drug was given to President Donald Trump when he contracted COVID-19.

28. The FDA approved the drug on October 22, 2020, on a fast-track basis pursuant to Gilead's representations that the drug was safe and effective against COVID-19 as part of its submissions on August 7, 2020 (NDA 214787).

29. The average cost of Remdesivir as set by Gilead ranged between $390-$520 per vial or $2,340-$3,120 for a full five-day course of treatment.

30. At the time that FDA approved the drug, there was no indication of glass particles (foreign body) being present in the drug composition.

31. Upon information and belief, Gilead did not disclose and/or misrepresented to the FDA about the possibility of glass particles (foreign body) being present in the drug composition and/or some batches thereof which could cause serious adverse events such as, stroke and/or death.

32. Gilead represented to FDA that its drug quality was appropriate and the proposed facilities for drug manufacturing had satisfactory Current Good Manufacturing Practices (cGMP).

33. The FDA's decision to approve the drug was based on results of three randomized clinical trials funded and/or performed by Gilead that showed that Remdesivir could reduce mortality and improve outcomes.

34. The FDA approval came within two weeks after World Health Organization (WHO) rejected the use of Remdesivir based on its solidarity trial conducted in approximately 405 hospitals in 30 countries where it was determined that Remdesivir did not improve mortality and outcome in patients suffering from COVID-19. In fact, WHO raised concerns regarding Remdesivir causing more harm based on complaints of liver and kidney problems in patients who received the drug.

35. The FDA typically convenes an independent advisory committee to review drugs prior to approval if there are questions regarding the drug's efficacy or safety but did not so for Remdesivir despite strong public contention that an independent committee be impaneled to review the drug's efficacy. **(Public Citizen Letter, Exhibit 3).** The agency instead stated that it

was not necessary because Gilead's application for approval did not raise significant safety or efficacy issues. **(FDA response, Exhibit 4).**

36. Prior to receiving FDA approval, Remdesivir had received an emergency-use authorization in May 2020 after preliminary data from governmental trial, run by NIH's National Institute of Allergy and Infectious Diseases, showed that Remdesivir cut the length of hospital stays.

37. Upon information and belief, and based on information currently available in the public domain, several panel members of NIH that served as research support and/or on the advisory board had financial ties with Gilead. **(Panel Roster/Financial Disclosure, Exhibit 5).**

38. Upon information and belief, had FDA known about the potential for Remdesivir to contain glass particles (foreign body) prior to the drug being introduced in the stream of commerce, it would have withheld and/or withdrawn its approval until such time that Gilead took appropriate measure to eliminate the risk of glass particles (foreign body) being present in the drug.

39. The Remdesivir drug administered to Dan during his admission to St. Joseph Mercy hospital was not in accordance with Gilead's FDA approval for the drug in terms of its manufacturing quality and/or labeling.

COUNT I – BREACH OF IMPLIED WARRANTY (GILEAD)

The Plaintiffs restates, realleges, and incorporates by reference each and every paragraph set forth above, as though fully set forth herein, and further states, in the alternative, the following:

40. At all times pertinent to this complaint, the Remdesivir drug administered to Dan contained glass particles (foreign body) and was not reasonably fit for its intended, anticipated, or reasonably foreseeable use at the time it left Gilead's control.

41. At all times pertinent to this complaint, Gilead acknowledged in the recall that the glass particles were known to cause adverse events such as, stroke and/or death if they became lodged in a blood vessel.

42. At all times pertinent to this complaint, the U.S. Food and Drug Administration (FDA) did not approve Remdesivir with presence of glass particles (foreign body) when the drug received its questionable FDA approval.

43. At all times pertinent to this complaint, Gilead did not inform FDA prior to introducing Remdesivir into the stream of commerce about the possibility of glass particles (foreign body) being present in the drug and/or some batches thereof which would have undermined its safety and efficacy and caused FDA to withhold and/or withdraw its approval.

44. At all times pertinent to this complaint, Gilead recalled the affected lots containing glass particles with the knowledge of FDA clearly indicating that FDA did not approve Remdesivir with presence of glass particles (foreign body) given its potential adverse effects.

45. At all times pertinent to this complaint, the Remdesivir drug administered to Dan during his admission to St. Joseph Mercy hospital was not in accordance Gilead's FDA approval for the drug in terms of its manufacturing quality and/or labeling as it contained glass particles (foreign body).

46. At all times pertinent to this complaint, Dan and/or others similarly situated were entitled to rely upon the implied warranty of fitness and suitability, which attended the design, manufacture, distribution, labeling, and sale of the Remdesivir drug.

47. At all times pertinent to this complaint, Dan suffered serious injuries as a result of his reliance on the implied warranty of fitness and suitability, which attended the design, manufacture, distribution, labeling, and sale of Remdesivir drug.

48. As a direct and proximate result of the breach of implied warranty, Dan suffered the following injuries and damages:

a. Stroke and associated sequelae.

b. Leg amputation.

c. Pain and suffering, past, present, and future;

d. Disability and disfigurement, past, present, and future;

e. Emotional distress and anxiety, past, present, and future;

f. Denial of social pleasures and enjoyments;

g. Medical expenses, past, present, and future;

h. Loss of wages and earnings capacity, past, present, and future;

i. Attendant care and replacement services, past, present, and future;

j. Other injuries and damages to be determined through the course of discovery and described in Dan's medical records.

WHEREFORE, the Plaintiffs respectfully requests that this Honorable Court enter a judgment against Gilead in any amount in excess of TWENTY-FIVE THOUSAND ($25,000) DOLLARS, together with interest, costs, and attorney fees, to which the Plaintiff is deemed to be entitled.

COUNT II – BREACH OF EXPRESS WARRANTY (GILEAD)

The Plaintiffs restates, realleges, and incorporates by reference each and every paragraph set forth above, as though fully set forth herein, and further states, in the alternative, the following:

49. At all times pertinent to this complaint, Gilead expressly warranted, through its marketing, advertising, distributors, and sales representatives that Remdesivir was of merchantable quality and fit for the ordinary purposes and uses for which it was sold.

50. These statements made constitute express warranties regarding the Remdesivir drug.

51. At all times pertinent to this complaint, Gilead breached these express warranties by designing, labeling, manufacturing, and selling defective and unreasonably dangerous Remdesivir drug containing glass particles (foreign body) that was neither of merchantable quality nor fit for the ordinary purposes for which it was sold, presenting an unreasonable risk of injury to patients, including Dan, during foreseeable use.

52. Notwithstanding those statements, the Remdesivir drug containing glass particles (foreign particles) was sold in breach of the attendant express warranties.

53. Gilead knew, or should have known, at the time Remdesivir drug containing glass particles (foreign body) left its control that it was defective and dangerous and there was a substantial likelihood that the glass particles would cause serious injuries which form the basis for this action.

54. At all times pertinent to this complaint, Dan and/or others similarly situated were entitled to rely upon and did rely upon the express warranties which attended the sale of Remdesivir drug.

55. Dan suffered serious injuries as a result of his and St. Joseph Mercy hospital's reliance on the express warranties which attended the sale of defective Remdesivir drug containing glass particles (foreign body).

56. As a direct and proximate result of the breach of express warranties, Dan suffered the following injuries and damages:

a. Stroke and associated sequelae.

b. Leg amputation.

c. Pain and suffering, past, present, and future;

d. Disability and disfigurement, past, present, and future;

e. Emotional distress and anxiety, past, present, and future;

f. Denial of social pleasures and enjoyments;

g. Medical expenses, past, present, and future;

h. Loss of wages and earnings capacity, past, present, and future;

i. Attendant care and replacement services, past, present, and future;

j. Other injuries and damages to be determined through the course of discovery and described in Dan's medical records.

WHEREFORE, the Plaintiffs respectfully requests that this Honorable Court enter a judgment against Gilead in any amount in excess of TWENTY-FIVE THOUSAND ($25,000) DOLLARS, together with interest, costs, and attorney fees, to which the Plaintiff is deemed to be entitled.

COUNT III – NEGLIGENCE (GILEAD)

The Plaintiffs restates, realleges, and incorporates by reference each and every paragraph set forth above, as though fully set forth herein, and further states, in the alternative, the following:

57. At all times pertinent to this complaint, Gilead owed the general public including, Dan a duty to appropriately design, label, manufacture, assemble, inspect, test, and market Remdesivir drug free from glass particles (foreign body).

58. Notwithstanding the said obligation, and in breach thereof, Gilead was negligent in design, manufacture, assembly, testing, marketing, labeling, packaging, inspecting, and sale of the Remdesivir drug at the time it left Gilead's control, in the manner set forth below:

a. Failed to test and/or inspect the drug for presence of glass particles before placing it into the stream of commerce.

b. Failed to have a manufacturing and/or assembly process that would eliminate the possibility of glass particles from entering the drug composition.

c. Failed to include appropriate warning label on the drug apprising the medical providers and/or ultimate users of the possibility of presence of glass particles (foreign body) in the drug and their adverse effects on health.

d. Failed to disclose and/or misrepresented to FDA about the possibility of glass particles (foreign body) being present in the drug composition during manufacturing and/or assembly process which would have undermined its safety and efficacy and would have caused FDA to withhold and/or withdraw its approval.

e. Improperly obtaining FDA approval in the first place by submitting results of self-funded randomized control trials, in part, overseen by NIH where several members of NIH had financial ties to Gilead.

f. Others acts or omissions that may be revealed through discovery.

59. At all times pertinent to this complaint, Gilead knew or should have known that the Remdesivir drug containing glass particles (foreign body) was defective at the time it left its control and there was a substantial likelihood that the glass particles would cause serious injuries which form the basis for this action.

60. As a direct and proximate result of the aforementioned negligent acts and/or omissions, Dan suffered the following injuries and damages:

a. Stroke and associated sequelae.

b. Leg amputation.

c. Pain and suffering, past, present, and future;

d. Disability and disfigurement, past, present, and future;

e. Emotional distress and anxiety, past, present, and future;

f. Denial of social pleasures and enjoyments;

g. Medical expenses, past, present, and future;

h. Loss of wages and earnings capacity, past, present, and future;

i. Attendant care and replacement services, past, present, and future;

j. Other injuries and damages to be determined through the course of discovery and described in Dan's medical records.

WHEREFORE, the Plaintiffs respectfully requests that this Honorable Court enter a judgment against Gilead in any amount in excess of TWENTY-FIVE THOUSAND ($25,000) DOLLARS, together with interest, costs, and attorney fees, to which the Plaintiff is deemed to be entitled.

COUNT IV – GROSS NEGLIGENCE (GILEAD)

The Plaintiffs restates, realleges, and incorporates by reference each and every paragraph set forth above, as though fully set forth herein, and further states, in the alternative, the following:

61. At all times pertinent to this complaint, Gilead owed the general public including, Dan a duty to appropriately design, label, manufacture, assemble, inspect, test, and market Remdesivir drug free from glass particles (foreign body).

62. At all times pertinent to this complaint, Gilead was grossly negligent and acted in wanton disregard for the safety of the consumers of Remdesivir including Dan and his medical providers, out of concern for its pecuniary benefit.

63. At all times pertinent to this complaint, Gilead knew or should have known that the Remdesivir drug containing glass particles (foreign body) was defective and there was a substantial likelihood that the glass particles would cause serious injuries which form the basis for this action.

64. At all times pertinent to this complaint, Gilead introduced Remdesivir drug containing glass particles (foreign body) into the stream of commerce knowing fully well that the glass particles could cause serious injuries such as, stroke and/or even death.

65. The above-cited conduct was so reckless so as to demonstrate a substantial lack of concern for whether an injury resulted to consumers such as, Dan from consuming Remdesivir with glass particles (foreign body).

66. As a direct and proximate result of the aforementioned grossly negligent acts, Dan suffered the following injuries and damages:

a. Stroke and associated sequelae.

b. Leg amputation.

c. Pain and suffering, past, present, and future;

d. Disability and disfigurement, past, present, and future;

e. Emotional distress and anxiety, past, present, and future;

f. Denial of social pleasures and enjoyments;

g. Medical expenses, past, present, and future;

h. Loss of wages and earnings capacity, past, present, and future;

i. Attendant care and replacement services, past, present, and future;

j. Other injuries and damages to be determined through the course of discovery and described in Dan's medical records.

WHEREFORE, the Plaintiffs respectfully requests that this Honorable Court enter a judgment against Gilead in any amount in excess of TWENTY-FIVE THOUSAND ($25,000) DOLLARS, together with interest, costs, and attorney fees, to which the Plaintiff is deemed to be entitled.

COUNT V – INTENTIONAL MISREPRESENTATION (GILEAD)

The Plaintiffs restates, realleges, and incorporates by reference each and every paragraph set forth above, as though fully set forth herein, and further states, in the alternative, the following:

67. At all times pertinent to this complaint, Gilead owed the general public including, Dan a duty to appropriately design, label, manufacture, assemble, inspect, test, and market Remdesivir drug free from glass particles (foreign body).

68. At all times pertinent to this complaint, Gilead through its application for fast-track FDA approval represented to the FDA that Remdesivir was safe and effective against COVID-19.

69. At all times pertinent to this complaint, Gilead through its application for fast-track FDA approval represented to the FDA that Remdesivir drug composition and manufacturing processes were appropriate.

70. At all times pertinent to this complaint, Gilead through its application for fast-track FDA approval represented to the FDA that the proposed facilities for Remdesivir manufacturing were satisfactory and in accordance with Current Good Manufacturing Practices (cGMP).

71. At all times pertinent to this complaint, Gilead knew or had reason to know that its representations were not accurate and that there was a possibility of glass particles (foreign body) being present in Remdesivir due to its manufacturing and/or assembly process which would undermine its safety and efficacy and, therefore, would not receive FDA approval.

72. At all times pertinent to the complaint, Gilead had a duty to disclose the possibility of glass particles (foreign body) being present in Remdesivir and breached said duty when it failed to make any reference in its submissions to FDA for drug approval clearly for its pecuniary benefit.

73. As a direct and proximate result of the aforementioned acts and/or omissions, Dan suffered the following injuries and damages:

a. Stroke and associated sequelae.

b. Leg amputation.

c. Pain and suffering, past, present, and future;

d. Disability and disfigurement, past, present, and future;

e. Emotional distress and anxiety, past, present, and future;

f. Denial of social pleasures and enjoyments;

g. Medical expenses, past, present, and future;

h. Loss of wages and earnings capacity, past, present, and future;

i. Attendant care and replacement services, past, present, and future;

j. Other injuries and damages to be determined through the course of discovery and described in Dan's medical records.

WHEREFORE, the Plaintiffs respectfully requests that this Honorable Court enter a judgment against Gilead in any amount in excess of TWENTY-FIVE THOUSAND ($25,000) DOLLARS, together with interest, costs, and attorney fees, to which the Plaintiff is deemed to be entitled.

COUNT VI – NEGLIGENCE (ST. JOSEPH MERCY HOSPITAL)

The Plaintiffs restates, realleges, and incorporates by reference each and every paragraph set forth above, as though fully set forth herein, and further states, in the alternative, the following:

74. At all times pertinent to this complaint, St. Joseph Mercy hospital through its president, chief medical officer, hospital administrator, and/or other employees, agents, and/or representatives owed Dan a duty to expeditiously warn or inform him and/or his family members that Dan had received Remdesivir drug containing glass particles (foreign body) so that his subsequent treating physicians could provide appropriate treatment.

75. Notwithstanding the said obligation, and in breach thereof, St. Joseph Mercy hospital through its president, chief medical officer, hospital administrator, and/or other employees, agents, and/or representatives was negligent in the manner set forth below:

a. Failed to immediately warn or inform Dan and/or his family members after receiving Gilead's recall notification dated December 3, 2020, that Dan was administered the affected Remdesivir drug (Lot #2141001-1A) containing glass particles (foreign body) which was responsible for his stroke.

b. Failed to immediately warn or inform Dan and/or family members as indicated by Gilead in the recall notification to seek immediate medical help relating to adverse effects from administration of Remdesivir drug containing glass particles (foreign body).

c. Other acts or omissions that may be revealed through discovery.

76. As a direct and proximate result of the aforementioned negligent acts and/or omissions, Dan suffered the following injuries and damages:

a. Second stroke on or about December 14, 2021, and associated sequelae.

b. Leg amputation.

c. Pain and suffering, past, present, and future;

d. Disability and disfigurement, past, present, and future;

e. Emotional distress and anxiety, past, present, and future;

f. Denial of social pleasures and enjoyments;

g. Medical expenses, past, present, and future;

h. Loss of wages and earnings capacity, past, present, and future;

i. Attendant care and replacement services, past, present, and future;

j. Other injuries and damages to be determined through the course of discovery and described in Dan's medical records.

WHEREFORE, the Plaintiffs respectfully requests that this Honorable Court enter a judgment against St. Joseph Mercy hospital in any amount in excess of TWENTY-FIVE THOUSAND ($25,000) DOLLARS, together with interest, costs, and attorney fees, to which the Plaintiff is deemed to be entitled.

COUNT VII – GROSS NEGLIGENCE (ST. JOSEPH MERCY HOSPITAL)

The Plaintiffs restates, realleges, and incorporates by reference each and every paragraph set forth above, as though fully set forth herein, and further states, in the alternative, the following:

77. At all times pertinent to this complaint, St. Joseph Mercy hospital through its president, chief medical officer, hospital administrator, and/or other employees, agents, and/or representatives owed Dan a duty to expeditiously warn or inform him and/or his family members that Dan had received Remdesivir drug containing glass particles (foreign body) so that his subsequent treating physicians could provide appropriate treatment.

78. At all times pertinent to this complaint, St. Joseph Mercy hospital was grossly negligent and acted in wanton disregard for the safety of the consumers of Remdesivir including Dan by failing to immediately notify him about the fact that he had received several doses of Remdesivir containing glass particles (foreign body) which was responsible for his stroke.

79. The above-cited conduct was so reckless so as to demonstrate a substantial lack of concern for whether an injury resulted to consumers such as, Dan from consuming Remdesivir with glass particles (foreign body).

80. As a direct and proximate result of the aforementioned grossly negligent acts, Dan suffered the following injuries and damages:

a. Stroke and associated sequelae.

b. Leg amputation.

c. Pain and suffering, past, present, and future;

d. Disability and disfigurement, past, present, and future;

e. Emotional distress and anxiety, past, present, and future;

f. Denial of social pleasures and enjoyments;

g. Medical expenses, past, present, and future;

h. Loss of wages and earnings capacity, past, present, and future;

i. Attendant care and replacement services, past, present, and future;

j. Other injuries and damages to be determined through the course of discovery and described in Dan's medical records.

WHEREFORE, the Plaintiffs respectfully requests that this Honorable Court enter a judgment against St. Joseph Mercy hospital in any amount in excess of TWENTY-FIVE THOUSAND ($25,000) DOLLARS, together with interest, costs, and attorney fees, to which the Plaintiff is deemed to be entitled.

COUNT VIII – LOSS OF CONSORTIUM (KATHLEEN P. NOWACKI)

The Plaintiffs restates, realleges, and incorporates by reference each and every paragraph set forth above, as though fully set forth herein, and further states, in the alternative, the following:

81. At all times pertinent to this complaint, Kathleen P. Nowacki, was the lawfully wedded wife of Daniel Nowacki.

82. As a direct and proximate result of injuries suffered by Dan because of the glass particles (foreign body) in the Remdesivir drug, Kathleen has suffered and will continue to suffer the loss of consortium including, the loss of her husband's society, companionship, and household services.

WHEREFORE, the Plaintiffs respectfully requests that this Honorable Court enter a judgment against the Defendants in any amount in excess of TWENTY-FIVE THOUSAND ($25,000) DOLLARS, together with interest, costs, and attorney fees, to which the Plaintiff is deemed to be entitled.

Respectfully submitted,

JOHNSON LAW, PLC

By: */s/ Kanwarpreet S. Khahra*

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VEN R. JOHNSON (P39219)
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Dated: December 28, 2022

EXHIBIT 1

ST. JOSEPH MERCY
CHELSEA

775 South Main Street
Chelsea, MI 48118
734-593-6000

April 6th, 2022

Mr. Mark Nowacki
29 Twin Lakes Dr.
Onsted, MI 49265

RE: Administration of Recalled Remdesivir to Mr. Daniel Nowacki

Dear Mr. Mark Nowacki,

Thank you for your inquiry regarding whether or not your father, Mr. Daniel Nowacki received any of the drug Remdesivir which is subject to the manufacturer Gilead's voluntary recall. We apologize for the delay in responding as we had to research this further in order to verify the information. Our records indicate Mr. Daniel Nowacki was in the hospital between November 10, 2021 and November 24, 2021 and did receive the medication that is subject to the recall. The recall announcement was dated December 3, 2021 and when Mr. Daniel Nowacki was given Remdesivir we were not yet aware of the recall.

Two of the five doses in the course of treatment received by Mr. Daniel Nowacki involved the recalled lot #'s. Those doses were administered on November 10th, 2021 (lot #2141001-1a) and November 11th, 2021 (lot #2141001-1a). The other doses with corresponding lot #'s were as follows; November 12th, 2021 (lot #27015BFA), November 13th, 2021 (lot #27015BFA) and November 14th, 2021 (lot #27015BFA).

If you have any questions regarding health concerns, we recommend you follow up with your primary care provider. Additionally, we are including Gilead's recall announcement for your information.

Sincerely,

Jennifer Rodriguez, PharmD
Inpatient Pharmacy Manager
St. Joseph Mercy Chelsea

Enclosure

EXHIBIT
A

EXHIBIT 2

COMPANY ANNOUNCEMENT

Gilead Issues A Voluntary Nationwide Recall of Two Lots of Veklury® (Remdesivir) Due to Presence of Glass Particulates

This recall has been completed and FDA has terminated this recall.

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

Read Announcement | View Product Photos

Summary

Company Announcement Date:

December 03, 2021

FDA Publish Date:

December 03, 2021

Product Type:

Drugs

Reason for Announcement:

Presence of glass particulates

Company Name:

Gilead Sciences Inc.

Brand Name:

Gilead

Product Description:

Veklury® (remdesivir 100 mg for injection)

Company Announcement

Foster City, CA, Gilead Sciences Inc. (Nasdaq: GILD) today announced it is voluntarily recalling two lots of Veklury® (remdesivir 100 mg for injection) to the user level. Gilead Sciences Inc. received a customer complaint, confirmed by the firm's investigation, of the presence of glass

particulates.

Risk Statement: The administration of an injectable product that contains glass particulates may result in local irritation or swelling in response to the foreign material. If the glass particulate reaches the blood vessels it can travel to various organs and block blood vessels in the heart, lungs or brain which can cause stroke and even lead to death. To date, Gilead Sciences Inc. has not received any reports of adverse events related to this recall.

Veklury is indicated for the treatment of adults and pediatric patients ≥ 12 years old and weighing ≥40 kg requiring hospitalization for COVID-19. The lyophilized form of Veklury (remdesivir 100 mg for injection) is distributed in single dose clear glass vials in powder form and reconstituted at the site of use. Veklury lots 2141001-1A and 2141002-1A were distributed nationwide in the United States, beginning October 2021. NDC, lot, expiration date and distribution dates can be found in the table below.

Product Description	NDC	Lot #	Expiration Date	Distribution date to wholesalers
Veklury® (remdesivir 100mg for injection)	61958-2901-02	2141001-1A 2141002-1A	01/2024 01/2024	10/25/21-10/26/2021 10/26/21-11/02/2021

Gilead is notifying its distributors and customers via UPS next day air mail to hospital pharmacies and is facilitating the return of any remaining vials from the affected lots. Hospitals that have Veklury which is being recalled should stop using the affected lots and return the product vials per the instructions.

Consumers with questions regarding this recall can contact Gilead Medical Information at 1-866-633-4474 Monday to Friday 6am - 4pm PST or through their website at www.askgileadmedical.com. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda)
- Regular Mail or Fax: Download form (/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting) or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

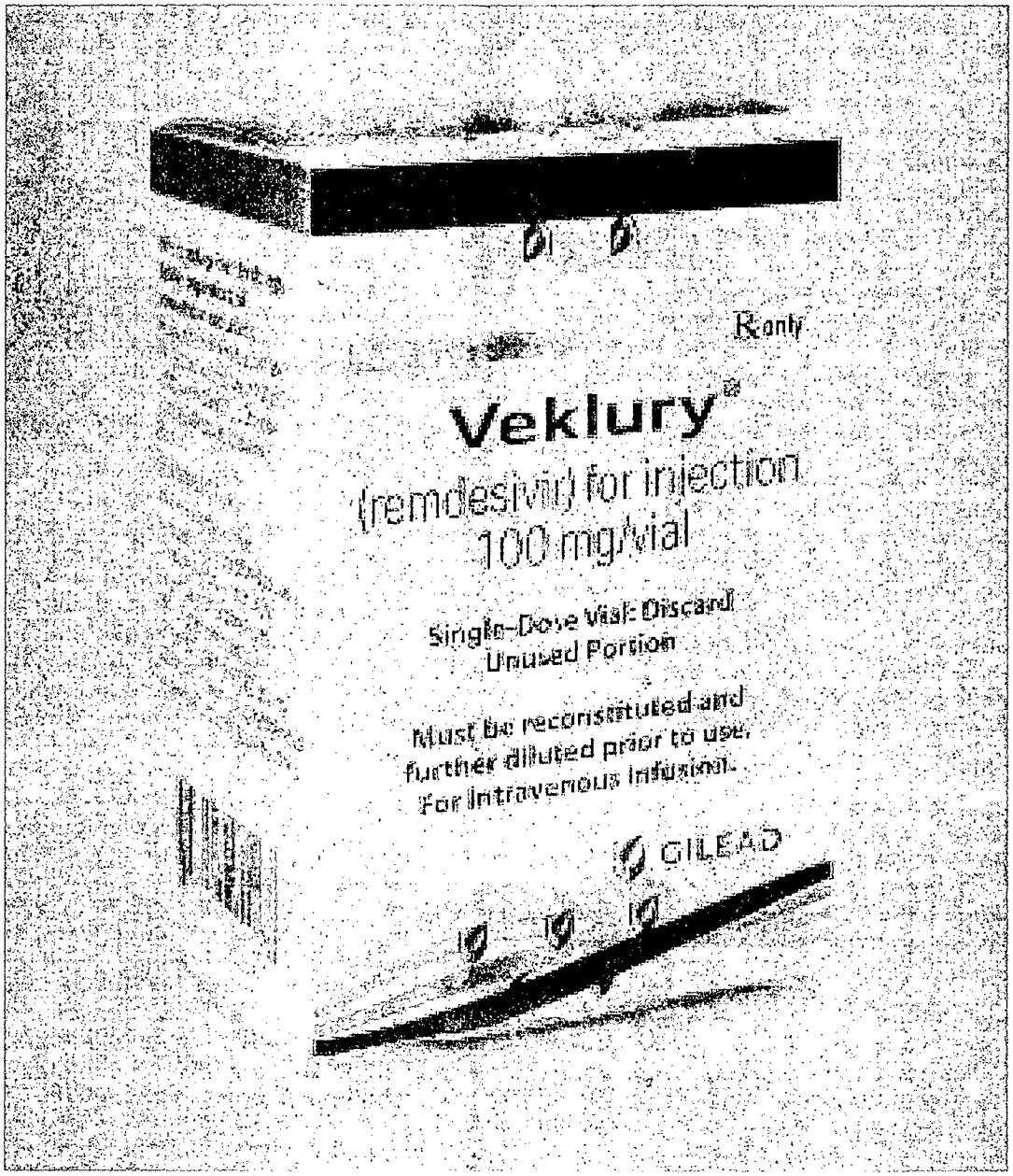
Company Contact Information

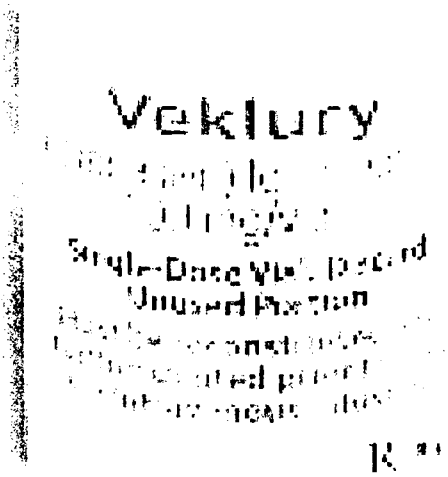
Consumers:

Gilead Medical Information

1-866-633-4474

Product Photos




Veklury

More Recalls, Market Withdrawals, & Safety Alerts (/safety/recalls-market-withdrawals-safety-alerts)

EXHIBIT 3

PUBLICCITIZEN

1600 20th Street, NW • Washington, D.C. 20009 • 202/588-1000 • www.citizen.org

April 21, 2021

Janet Woodcock, M.D.
Acting Commissioner
Food and Drug Administration
U.S. Department of Health and Human Services
10903 New Hampshire Ave
Silver Spring, MD 20993

Patrizia Cavazzoni, M.D.
Director, Center for Drug Evaluation and Research
Food and Drug Administration
U.S. Department of Health and Human Services
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Acting Commissioner Woodcock and Director Cavazzoni:

Public Citizen, a consumer advocacy organization with more than 500,000 members and supporters nationwide, is writing to strongly disagree with the Food and Drug Administration's (FDA's) inexcusable failure to refer the new drug application (NDA) for remdesivir (VEKLURY) to the agency's Antimicrobial Drugs Advisory Committee prior to approving the drug on October 22, 2020, for adult and pediatric patients (12 years of age and older and weighing at least 40 kg) for the treatment of coronavirus disease 2019 (COVID-19) requiring hospitalization.[1]

That the FDA negligently avoided seeking advisory committee input is documented by the fact that prior to approving remdesivir, the agency had reviewed an October 15, 2020, preprint article that presented interim results of the World Health Organization (WHO) Solidarity trial, which was subsequently published in the *New England Journal of Medicine* online on December 2 and in print on February 11.[2] That large, multicenter, randomized clinical trial seriously challenged the FDA's conclusion that remdesivir is effective as a treatment for COVID-19. The WHO Solidarity trial investigators concluded, "Remdesivir...appeared to have little or no effect on hospitalized COVID-19, as indicated by overall mortality, initiation of ventilation and duration of hospital stay."[3]

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[1] Food and Drug Administration. Letter to Gilead Sciences, Inc., approving NDA 214787. October 22, 2020. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/214787Orig1s000ltr.pdf. Accessed April 19, 2021.

[2] WHO Solidarity Trial Consortium, et al. Repurposed antiviral drugs for Covid-19 — interim WHO Solidarity Trial results. *N Eng J Med*. 2021;384(6):497-511.

[3] WHO Solidarity Trial Consortium, et al. Repurposed antiviral drugs for Covid-19 — interim WHO SOLIDARITY trial results. https://www.medrxiv.org/content/10.1101/2020.10.15.20209817v1. Accessed April 19, 2021.

We therefore urge you to promptly convene a meeting of the FDA's Antimicrobial Drugs Advisory Committee to evaluate all currently available evidence regarding the safety, efficacy, and real-world effectiveness of remdesivir and to consider whether the approval of the drug should be rescinded.

Background on statutory requirements for convening FDA advisory committee meetings prior to approval of new drugs

Section 505(s) of the Food, Drug, and Cosmetic Act (FDCA; 21 U.S.C. 355(s)) requires the following:

> Prior to the approval of a drug no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under this section or section 262 of title 42, the Secretary shall-
>
> (1) refer such drug to an FDA advisory committee for review at a meeting of such advisory committee; or
>
> (2) if the Secretary does not refer such a drug to an FDA advisory committee prior to the approval of the drug, provide in the action letter on the application for the drug a summary of the reasons why the Secretary did not refer the drug to an advisory committee prior to approval.

Under section 505(n) of the FDCA (21 U.S.C. 355(n)), a major purpose of FDA advisory committees is to provide independent expert scientific advice and recommendations to the agency regarding the approval for marketing of a drug.

Historically, the FDA has routinely referred to its advisory committees first-in-class new drugs prior to their initial approval for marketing. Moreover, the public-at-large, including members of the U.S. Congress, have come to regard advisory committee review as a critical step in the FDA's evaluation of complex or high-profile NDAs. One group of seven U.S. senators recently wrote in a letter to President Biden, "The FDA convenes an advisory committee of scientific experts when a matter is of significant public interest, highly controversial, or in need of a specific type of expertise."[4] Consideration of the first purported drug therapy for a deadly global pandemic disease very plausibly checks all three of these rationales for convening an advisory committee meeting.

FDA's unacceptable decision not to refer the NDA for remdesivir to the Antimicrobial Drugs Advisory Committee prior to approval

The FDA decided not to refer the NDA for remdesivir to the Antimicrobial Drugs Advisory Committee prior to approving the drug in October 2020. The approval letter to Gilead Sciences, Inc., for remdesivir included the following boilerplate text explaining the agency's decision:

[4] Manchin J, Hassan MW, King AS, et al. Letter to President Biden regarding the ongoing opioid epidemic. March 26, 2021. https://www.manchin.senate.gov/imo/media/doc/210326%20Letter%20to%20WH%20Re%20FDA%20Opioids.pdf. Accessed April 19, 2021.

> Your application for VEKLURY was not referred to an FDA advisory committee because the application did not raise significant safety or efficacy issues that were unexpected for the drug in the intended population and did not raise significant public health questions on the role of the drug in the diagnosis, cure, mitigation, treatment, or prevention of a disease.[5]

This stated rationale that an advisory committee was not needed because the application did not raise significant efficacy issues was directly refuted by the lack of substantial evidence of effectiveness for remdesivir in the WHO Solidarity trial. As such, it is unacceptable that the agency evaded seeking input from the independent experts on the Antimicrobial Drugs Advisory Committee and from the public through the open public hearing that would have been part of an advisory committee process, particularly when the drug in question already was being made widely available to patients in the U.S. under an Emergency Use Authorization (EUA) granted on May 1, 2020.[6]

The main beneficiary of the highly debatable decision to approve remdesivir seems to be Gilead Sciences, which presently is earning massive, monopoly-protected profits[7] thanks to the premature full approval by the FDA. Notably, unlike the COVID-19 vaccines, which all require vetting by the FDA's Vaccine and Related Biological Products Advisory Committee prior to the issuance of an EUA, remdesivir was granted full approval status without any such independent expert input.

Efficacy data included in the initial NDA for remdesivir

FDA approval of remdesivir was based on five clinical trials, three formally submitted as part of the sponsor's NDA, and two third-party studies. The FDA reviewers described marginal and sometimes confusing results from these trials, but they still somehow determined that the "overall benefit-risk profile of [remdesivir] is favorable"[8] and that there was "substantial evidence of effectiveness."[9] That insupportable conclusion thus far stands without advisory committee input, even as the FDA summary review noted that remdesivir "would be the first

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[5] Food and Drug Administration. Letter to Gilead Sciences, Inc., approving NDA 214787. October 22, 2020. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/214787Orig1s000ltr.pdf. Accessed April 19, 2021.

[6] Food and Drug Administration. Letter to Gilead Sciences, Inc., reissuing an Emergency Use Authorization for emergency use of remdesivir for the treatment of hospitalized COVID-19 patients younger than aged 12. October 22, 2020. https://www.fda.gov/media/137564/download. Accessed April 19, 2021.

[7] Tribble, SJ. Remdesivir, given to halt of hospitalized Covid patients in the U.S., is big win for Gilead — Boosted by taxpayers. Kaiser Health News, January 27, 2021. https://khn.org/news/article/remdesivir-given-to-half-of-hospitalized-covid-patients-in-u-s-is-big-win-for-gilead-boosted-by-taxpayers/. Accessed April 19, 2021.

[8] Food and Drug Administration, Center for Drug Evaluation and Research. Summary review. Application number: 214787Orig1s000. October 21.2020. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/214787Orig1s000SumR.pdf. Accessed April 19, 2021.

[9] Food and Drug Administration, Center for Drug Evaluation and Research. Clinical Review(s). Application number: 214787Orig1s000. September 16, 2020. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/214787Orig1s000MedR.pdf. Accessed April 19, 2021

drug approved by the US Food and Drug Administration (FDA) for the treatment of COVID-19."[10]

The primary efficacy data that supported the FDA's October 2020 approval of remdesivir came from the National Institute of Allergy and Infectious Diseases-sponsored pivotal phase 3 clinical trial designated as the Adaptive COVID-19 Treatment Trial (ACTT-1). Two trials sponsored by Gilead Sciences (trial identifiers: GS-US-540-5774 and GS-US-540-5773) also were used to evaluate remdesivir's efficacy for this NDA.

ACTT-1

ACTT-1 (NCT04280705) was a multinational, randomized, double-blind, placebo-controlled trial that evaluated the safety and efficacy of remdesivir in hospitalized patients with mild-to-severe COVID-19.[11] Subjects (n=1,062) were evenly randomized into a remdesivir or a placebo group, receiving such therapy for up to 10 days. The primary efficacy endpoint of this trial was time to recovery through day 29, based on an eight-point ordinal scale ranging from discharge with no limitation on activities (score=1) to death (score=8). A secondary outcome was mortality through day 29, though it notably was neither a pre-specified primary nor a key secondary endpoint of this trial.

ACTT-1 found that remdesivir exposure increased the 29-day recovery rate (recovery rate ratio 1.29; 95% confidence interval [CI]: 1.12,1.49; $p< 0.001$), corresponding to median days to recovery that favored remdesivir (10 days; 95% CI: 9,11) over placebo (15 days; 95% CI: 13,18) by only five days. A subgroup analysis showed that the improvement in the primary efficacy outcome with remdesivir versus placebo was only statistically significant for subjects requiring hospital-based medical care and supplemental oxygen but not those with more severe (requiring high-flow oxygen, non-invasive ventilation, invasive mechanical ventilation, or extracorporeal membrane oxygenation [ECMO]).

Mortality results for ACTT-1 showed that at 29 days, 11% of the remdesivir-group subjects had died versus 15% of the placebo-group subjects, a difference that was not statistically significant [hazard ratio 0.73; 95% CI: 0.52,1.02; p=0.066].

Based on these data, the FDA clinical reviewers concluded that the "trial provided reliable and statistically persuasive evidence of benefit for [remdesivir] in hospitalized patients with COVID-19." The statistical reviewers concurred with that conclusion but noted that the data for remdesivir's efficacy in reducing mortality overall and morbidity or mortality in the subjects with the most severe COVID-19 were "inconclusive."

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[10] Food and Drug Administration, Center for Drug Evaluation and Research. Summary review. Application number: 214787Orig1s000. October 21.2020. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/214787Orig1s000SumR.pdf. Accessed April 19, 2021.

[11] *Ibid.*

Trial GS-US-54-5774

Trial GS-US-540-5774 (NCT04292730) was a multinational open-label trial that randomized 584 hospitalized subjects with moderate COVID-19 into one of three groups: five days of remdesivir, 10 days of remdesivir, or standard of care. The primary endpoint was clinical status on day 11 based on a seven-point ordinal scale ranging from death (score=1) to not hospitalized (score=7).[12] Moderate COVID-19 was defined as being hospitalized with laboratory-confirmed SARS-CoV-2 infection, radiographic evidence of pulmonary infiltrates, and oxygen saturation >94% on room air; patients with mechanical ventilation at screening were excluded. According to the FDA, this trial provided supportive evidence for the efficacy of remdesivir in patients with moderate COVID-19 illness, a group that made up a small proportion of the subject population (10%) enrolled in ACTT-1.[13]

The odds of improvement at 11 days for the five-day remdesivir group versus placebo was statistically significant (odd ratio [OR] 1.59; 95% CI: 1.00, 2.51; p=0.05), but statistically significant improvement was not seen for the 10-day course of the drug (OR=1.15; 95% CI: 0.75, 1.79; p=0.52). Corresponding rates of hospital discharge (fullest recovery measured) were 71%, 65%, and 62% for five-day remdesivir, 10-day remdesivir, and standard-of-care groups, respectively. No significant impact on mortality was evident as only two deaths in the entire trial occurred, both in the 10-day remdesivir group.

The overall assessment of the FDA clinical and statistical reviewers was that five-day remdesivir demonstrated significant time-to-recovery efficacy versus standard of care and that the 10-day course indicated a trend in that direction. FDA reviewers further noted that the open-label design of the trial may have biased the results against a significant 10-day effect because that course may have caused subjects to remain in the hospital longer than necessary.

Nevertheless, the failure to see a statistically significant improvement on the efficacy outcome for the 10-day course of remdesivir raises doubts about whether the drug provides clinically meaningful benefit for subjects with moderate COVID-19. Moreover, the open-label design arguably creates considerable bias in favor of remdesivir's efficacy, given the commercial and humanitarian hopes that naturally surrounded such a widely anticipated treatment.

Trial GS-US-540-5773

Trial GS-US-540-5773 (NCT0429899) was a multinational, open-label trial that evenly randomized 397 subjects with severe COVID-19 cases to receive either a five-day or 10-day course of remdesivir. A major limitation of this trial was the lack of a placebo or standard-of-care control group. Severe COVID-19 in this study was defined as being hospitalized with laboratory confirmed SARS-CoV-2 infection, radiographic evidence of pulmonary infiltrates, and oxygen saturation levels ≤94% on room air or requirement for supplemental oxygen. The

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[12] *Ibid.*

[13] Food and Drug Administration, Center for Drug Evaluation and Research. Statistical review(s). Application number: 214787Orig1s000. August 7, 2020. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/214787Orig1s000StatR.pdf. Accessed April 19, 2021.

primary endpoint was clinical status at day 14 on the same seven-point ordinal scale used for trial GS-US-540-5774.[14]

The trial found no statistically significant difference between the five-day and 10-day remdesivir groups with adjustment for differences in baseline on the primary efficacy outcome of clinical status at day 14, although the odds ratio for this outcome nominally favored the five-day course (OR 0.74; 95% CI: 0.5, 1.1; p=0.14).

Notably, a larger proportion of the 10-day remdesivir group subjects either died by day 14 or required invasive mechanical ventilation or ECMO on day 14 than did the five-day remdesivir subjects (28% versus 17%, respectively). Additionally, more 10-day remdesivir group subjects had either died or were receiving invasive mechanical ventilation or ECMO at day 28 compared with the five-day remdesivir subjects (23% versus 15%, respectively). Finally, more subjects in the 10-day remdesivir group discontinued treatment for nonfatal adverse events than those in the five-day remdesivir group (11% versus 5%, respectively).

The FDA clinical reviewers commented that the apparent trend toward better outcomes in the five-day remdesivir group may have been partially related to an imbalance in the baseline disease severity between the two groups; in particular, a significantly higher proportion of subjects in the 10-day remdesivir group required mechanical ventilation or high-flow oxygen at baseline.

The reviewers' overall assessment was that the results from this trial were "suggestive of a similar treatment effect with five-day and 10-day regimens in [the studied] population."[15] However, due to the lack of a control group, the magnitude of benefit could not be determined. Moreover, the conclusion was made that a five-day treatment course of remdesivir is sufficient, without acknowledging that the 10-day regimen in this trial nominally performed worse than the 5-day course on many important indicators.

Third-party trials

The FDA reviews of remdesivir also included discussion of two third-party clinical trials: a randomized, placebo-controlled trial conducted in China and the WHO's Solidarity trial.

Wang et al. (CO-US-540-5758; NCT04257656)

The FDA clinical and statistical reviews referenced an investigator-sponsored, randomized, double-blind, placebo-controlled clinical trial conducted in China that enrolled subjects with severe COVID-19 (within 12 days of illness onset, pneumonia confirmed by chest imaging, and oxygen saturation ≤94% on room air or a partial oxygen pressure/fraction of inspired oxygen

[14] Food and Drug Administration, Center for Drug Evaluation and Research. Clinical Review(s). Application number: 214787Orig1s000. September 16, 2020. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/214787Orig1s000MedR.pdf. Accessed April 19, 2021.

[15] *Ibid.*

ratio ≤300 mm Hg).[16,17,18] The primary outcome assessed was time to clinical improvement up to day 28 after randomization. Because public health measures in China controlled case rates so well, the trial was terminated before it could enroll the planned 453 subjects. Instead, only 237 subjects were enrolled and randomized to receive a 10-day course of either remdesivir (158 subjects) or a placebo (78 subjects).

The median time to clinical improvement was 21 days for the remdesivir group and 23 days for the placebo group, a difference that was not statistically significant (HR 1.23; 95% CI: 0.87, 1.75; p=0.24). The proportion of subjects with at least a two-point improvement on the six-point clinical status scale (death to hospital discharge) by day 28 was 65% in the remdesivir group versus 58% in the placebo group, a difference that also was not statistically significant (7.5%; 95% CI: -6, 20). In addition, the trial again revealed no mortality benefit as 14% of the remdesivir-group subjects died compared with 13% of the placebo-group subjects.

Although these efficacy findings were not statistically significant, the FDA statistical reviewers concluded that because this trial was much smaller than ACTT-1, there was a higher degree of uncertainty in estimating treatment effects. They further noted that "the point estimate for the remdesivir treatment effect was consistent with results from the adequate and well- controlled ACTT-1 using a similar time to improvement endpoint for the primary analysis. Thus, this trial was not considered to have provided discordant findings." A more appropriate assessment should have emphasized that the Chinese trial was uninformative because it enrolled only 237 of 453 needed subjects.

WHO Solidarity trial

The WHO Solidarity trial (NCT04315948) provided additional data that seriously challenges the FDA's conclusion that remdesivir is effective as a treatment for COVID-19. This trial used a randomized, open-label design that has involved up to five treatment arms (remdesivir, hydroxychloroquine, lopinavir, interferon beta-1a and local standard of care). Interim results from the trial were received by the FDA prior to approval and subsequently published online by the *New England Journal of Medicine* on December 2, 2020, and in print on February 11, 2021.[19]

The WHO Solidarity trial was conducted in 405 hospitals across 30 countries and the published analysis included randomized assignment of 2,750 adults to remdesivir and 2,708 to local standard of care. The primary outcome was in-hospital mortality. The only protocol-specified secondary outcomes were the initiation of mechanical ventilation and duration of hospital stay. Death occurred in 301 subjects in the remdesivir group and 303 subjects in the control group (rate ratio= 0.95, 95% CI: 0.81 to 1.11). For the prespecified secondary outcomes, remdesivir did

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[16] *Ibid.*

[17] Food and Drug Administration, Center for Drug Evaluation and Research. Statistical review(s). Application number: 214787Orig1s000. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/214787Orig1s000StatR.pdf. Accessed April 19, 2021.

[18] Wang Y, Zhang D, Du G, et al. Remdesivir in adults with severe COVID-19: a randomised, double-blind, placebo-controlled, multicentre trial. *Lancet*. 2020;395(10236):1569-1578.

[19] WHO Solidarity Trial Consortium, et al. Repurposed antiviral drugs for Covid-19 — interim WHO Solidarity Trial results. *N Eng J Med*. 2021;384(6):497-511.

not reduce the rate of mechanical ventilation or shorten the duration of hospitalization. Notably, mechanical ventilation initiation occurred in 295 (11%) of the remdesivir-group subjects and 284 (10%) of the control-group subjects receiving standard care.

Thus, this trial failed to show that remdesivir was effective in a real-world setting at decreasing mortality, mechanical ventilation initiation, or the duration of hospitalization, which are the key clinically meaningful outcomes in patients hospitalized with COVID-19.

In an October 22, 2020, addendum to the remdesivir NDA statistical review,[20] FDA statisticians made the following conclusion after reviewing a pre-print of the Solidarity preliminary results: "Collective results from the two trials [Solidarity and ACTT-1] are consistent with remdesivir having a neutral or small impact on all-cause mortality. While ACTT-1 results were suggestive of improved mortality, there remained residual statistical uncertainty, and the most straightforward interpretation of the two trials is that they have now ruled out a large mortality benefit."

The five aforementioned studies led FDA reviewers to conclude that remdesivir should be moved from EUA to fully approved status. This evidence-denying decision was made without input from an advisory committee despite conflicting evidence from the trials regarding whether the drug provides clinically meaningful benefit.

Conclusions and requested action

The FDA's decision not to refer the NDA for remdesivir (VEKLURY) to the agency's Antimicrobial Drugs Advisory Committee prior to approving the drug on October 22, 2020, failed to meet the criteria for avoiding such a meeting. The statement that "the application did not raise significant safety or efficacy issues" amounts to a wrongful dismissal of the evidence against remdesivir's effectiveness.

We therefore strongly urge you to promptly convene a meeting of the FDA's Antimicrobial Drugs Advisory Committee to evaluate all currently available evidence regarding the safety and effectiveness of remdesivir and to consider whether the approval of the drug should be rescinded. Potential actions that the advisory committee should consider recommending are the following:

- Take remdesivir completely off the market because of a lack of substantial evidence that it is effective.
- Rescind the approval of remdesivir but allow it to remain on the market only under a much more limited EUA unless its safety and efficacy can be established.

[20] Food and Drug Administration, Center for Drug Evaluation and Research. Statistical review(s). Application number: 214787Orig1s000. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/214787Orig1s000StatR.pdf. Accessed April 19, 2021.

Thank you for your attention to this important public health issue.

Sincerely,

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July 21, 2021

Michael T. Abrams, M.P.H., Ph.D.
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Dear Drs. Abrams, Carome, and Wolfe:

Thank you for your email and letter of April 21, 2021, to Drs. Woodcock and Cavazzoni in which you request that the Food and Drug Administration (FDA) convene an Antimicrobial Drugs Advisory Committee meeting to evaluate all currently available evidence regarding the safety and effectiveness of Veklury (remdesivir) and whether FDA approval of the drug should be rescinded.

Under the Federal Food, Drug & Cosmetic Act (FD&C Act) and FDA's implementing regulations, FDA has discretion in deciding whether to refer a matter to an advisory committee.[1] FDA acknowledges the important role that advisory committees can play in considering specified issues about a development program. However, as outlined below, due to the rigorous design of the ACTT-1 clinical trial in which Veklury demonstrated a robust, statistically significant treatment benefit compared to placebo for the clinically meaningful primary efficacy endpoint of time to recovery, we determined that there were no issues that necessitated referral to an advisory committee.[2]

As you mention in your letter, on October 22, 2020, FDA approved Veklury for use in adults and pediatric patients (12 years of age and older and weighing at least 40 kg) for the treatment of

[1] See section 505(s)(2) of the FD&C Act and 21 CFR part 14.
[2] See FDA's Approval Letter for NDA 214787 covering Veklury at:
https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/214787Orig1s000ltr.pdf

COVID-19 requiring hospitalization. As detailed in FDA's review memos for this application, the approval of Veklury was supported by the Agency's independent, in-depth analysis of data from three randomized, controlled clinical trials that included patients hospitalized with mild to severe COVID-19. This included the ACTT-1 trial sponsored by NIH's National Institute of Allergy and Infectious Diseases (NIAID) and the "SIMPLE" trials sponsored by Gilead Sciences Inc. The most compelling evidence of effectiveness was provided by the NIAID-sponsored ACTT-1 trial, given its rigorous trial design. [3,4,5,6,7]

The ACTT-1 trial was a randomized, placebo-controlled, double-blinded trial in hospitalized subjects with mild, moderate, or severe COVID-19 who received Veklury or placebo, in addition to standard of care. The primary goal of the ACTT-1 trial was to assess the time to recovery of hospitalized patients. Recovery was defined as either being discharged from the hospital or being hospitalized but not requiring supplemental oxygen and no longer requiring ongoing medical care. The median time to recovery from COVID-19 was 10 days for the Veklury group compared to 15 days for the placebo group, a strongly statistically significant difference. The odds of clinical improvement at Day 15 were also statistically significantly higher in the Veklury group compared to the placebo group. The overall 29-day mortality was 11% for the Veklury group compared to 15% for the placebo group; this difference was not statistically significant. FDA's review of the scientific evidence from the ACTT-1 trial, combined with its review of the "SIMPLE" trials sponsored by Gilead Sciences Inc., supported the Agency's determination that the standard for substantial evidence of effectiveness and demonstration of safety as required for the approval of a new drug application under section 505 of the FD&C Act was met and supported the approved indication.[8]

The SOLIDARITY trial was a World Health Organization-sponsored, open-label, randomized trial comparing different investigational interventions plus standard of care to standard of care alone in hospitalized patients with COVID-19. One of the drugs studied in SOLIDARITY was Veklury. The SOLIDARITY trial's primary goal was to assess for effects of treatment interventions on in-hospital mortality. The SOLIDARITY trial did not find a statistically significant difference in mortality between the Veklury arm and the standard-of-care arm. While both the SOLIDARITY trial and the ACTT-1 trial contribute to our understanding of interventions to help treat COVID-19, the two clinical trials had different trial designs and primary goals. The design of ACTT-1 (i.e., randomized, placebo-controlled, double-blinded) was better suited to rigorously assess a time to recovery endpoint compared to a trial with an open-

[3] Food and Drug Administration, Center for Drug Evaluation and Research. Summary review. Application number: 214787Orig1s000. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/214787Orig1s000SumR.pdf.
[4] Food and Drug Administration, Center for Drug Evaluation and Research. Statistical review(s). Application number: 214787Orig1s000 https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/214787Orig1s000StatR.pdf.
[5] Food and Drug Administration, Center for Drug Evaluation and Research. Clinical Review(s). Application number: 214787Orig1s000.https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/214787Orig1s000MedR.pdf.
[6] Rubin D, Chan-Tack K, Farley J, Sherwat A. FDA Approval of Remdesivir - A Step in the Right Direction. *N Engl J Med*. 2020;383(27):2598-2600 (https://www.nejm.org/doi/pdf/10.1056/NEJMp2032369).
[7] Frequently Asked Questions for Veklury (remdesivir). https://www.fda.gov/media/137574/download.
[8] See supra notes 3,4,5,6 and 7.

label design, such as the SOLIDARITY trial. Based on the findings of the ACTT-1 trial, combined with its review of the "SIMPLE" trials sponsored by Gilead Sciences Inc, FDA determined that Veklury provides clinical benefit to patients, including a shorter time to recovery and better odds of clinical improvement. The FDA carefully considered the results from SOLIDARITY and concluded that they do not refute the persuasive evidence of effectiveness from the randomized, placebo-controlled ACTT-1 trial.[9]

Thank you again for contacting FDA regarding this important matter.

Sincerely,

Patrizia Cavazzoni, M.D.
Director, Center for Drug Evaluation and Research

[9] Supra at Note 2.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Panel Member	Financial Disclosure	
	Company	Relationship
Danielle M. Campbell, MPH	Gilead Sciences	Advisory board
	GSK/ViiV Healthcare	Attendee at the community stakeholder meeting
Stephen V. Cantrill, MD	None	N/A
Kathleen Chiotos, MD, MSCE	None	N/A
Craig Coopersmith, MD	None	N/A
Page Crew, PharmD, MPH	None	N/A
Eric Daar, MD	Gilead Sciences	Consultant, research support
	GSK/ViiV Healthcare	Consultant, research support
	Merck & Co.	Consultant, research support
Demetre Daskalakis, MD, MPH	None	N/A
Richard T. Davey, Jr., MD	None	N/A
Laurie K. Doepel, BA	None	N/A
Amy L. Dzierba, PharmD	None	N/A
Derek Eisnor, MD	None	N/A
Gregory Eschenauer, PharmD	None	N/A
Laura Evans, MD, MSc	None	N/A
Joseph Francis, MD, MPH	None	N/A
John J. Gallagher, DNP, RN	None	N/A
Rajesh Gandhi, MD	None	N/A
David V. Glidden, PhD	None	N/A
Birgit Grund, PhD	None	N/A
Roy M. Gulick, MD, MPH	None	N/A
Alison Han, MD	None	N/A
Erica J. Hardy, MD, MMSc	None	N/A
Carly Harrison	AstraZeneca	Advisory board, consultant
	Aurinia Pharmaceuticals	Advisory board, stockholder
	UCB	Advisory board, consultant

Panel Member	Financial Disclosure	
	Company	Relationship
Lauren Henderson, MD, MMSc	Adaptive Biotechnologies	Consultant
	Bristol Myers Squibb	Research support
	Pfzer	External panel for grant reviews
	Sobi	Advisory board, consultant, research support
	Skygenic	Consultant, spouse is an employee
Elizabeth S. Higgs, MD, DTM&H, MIA	None	N/A
Carl Hinkson, MSRC	None	N/A
Brenna L. Hughes, MD, MSc	None	N/A
Steven Johnson, MD	GSK/ViiV Healthcare	Advisory board
Marla J. Keller, MD	None	N/A
Arthur Kim, MD	Kintor Pharmaceutical	Data and safety monitoring board chair/member
Safa Kurlakose, PharmD	None	N/A
H. Clifford Lane, MD	None	N/A
Jeffrey L. Lennox, MD	None	N/A
Andrea M. Lerner, MD, MS	None	N/A
Mitchell M. Levy, MD	None	N/A
Jonathan Li, MD, MMSc	None	N/A
Christine MacBrayne, PharmD, MSCS	None	N/A
Gregory Martin, MD, MSc	Genentech	Data and safety monitoring board chair/member
	Grifols	Research grants review panel
Henry Masur, MD	None	N/A
Susanna Naggie, MD, MHS	AbbVie	Research support, funding via NIH- supported trial
	Bristol Myers Squibb	Event adjudication committee
	FHI 360	Event adjudication committee
	Gilead Sciences	Research support
	Pardes Biosciences	Consultant

	Silverback Therapeutics Vir Biotechnology	Consultant Advisory board, stockholder, stock options
Martha C. Nason, PhD	None	N/A
Alice K. Pau, PharmD	None	N/A

Panel Member	Financial Disclosure	
	Company	Relationship
Andrew T. Pavia, MD	GSK	Advisory board
Michael Proschan, PhD	None	N/A
Renee Ridzon, MD	None	N/A
Grant Schulert, MD, PhD	Novartis	Honoraria
Nitin Seam, MD	None	N/A
Virginia Sheikh, MD, MHS	None	N/A
Steven Q. Simpson, MD	None	N/A
Kanal Singh, MD, MPH	None	N/A
Renee Stapleton, MD, PhD	Altimmune	Data and safety monitoring board chair
	CSL Behring	Consultant
Susan Swindells, MBBS	GSK/ViiV Healthcare	Research support
Pablo Tebas, MD	Gilead Sciences	Consultant
	GSK/ViiV Healthcare	Consultant
	Merck & Co.	Consultant
Phyllis Tien, MD, MSc	Eli Lilly	Research support
	Gilead Sciences	Research support
	Merck & Co.	Research support
Timothy M. Uyeki, MD, MPH	None	N/A
Alpana A. Waghmare, MD	AlloVir	Research support
	Ansun BioPharma	Research support
	Deverra Therapeutics	Data and safety monitoring board member
	KYORIN Pharmaceutical Co.	Advisory board
	Pfzer	Research support
	Vir Biotechnology	Research support
Jinoos Yazdany, MD, MPH	AstraZeneca	Consulting and research support related to lupus
	Aurinia	Consulting related to lupus drug
	Bristol Myers Squibb	Research support
	Pfzer	Consultant, lecture presenter

STATE OF MICHIGAN
IN THE CIRCUIT COURT FOR THE COUNTY OF WASHTENAW

MARK NOWACKI, as Legal Guardian and Conservator for DANIEL NOWACKI, and KATHLEEN NOWACKI,

Plaintiffs,

v.

GILEAD SCIENCES, INC., and ST. JOSEPH MERCY CHELSEA, INC., d/b/a ST. JOSEPH MERCY CHELSEA,

Defendants.

Civil Action No. 22-001761-NP

Honorable CAROL KUHNKE

JOHNSON LAW, PLC
Kanwarpreet S. Khahra (P80253)
Ven R. Johnson (P39219)
Attorneys for Plaintiff
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535 Griswold Street, Suite 26332
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DYKEMA GOSSETT PLLC
Bonnie Mayfield (P40275)
Attorney for Defendant Gilead Sciences, Inc., only
39577 Woodward Avenue, Suite 300
Bloomfield Hills, Michigan 48304
(248) 203-0700
bmayfield@dykema.com

APPEARANCE

TO: CLERK OF THE COURT
Kanwarpreet S. Khahra
Ven R. Johnson
Attorneys for Plaintiffs

PLEASE TAKE NOTICE that Bonnie Mayfield of the law firm of Dykema Gossett PLLC hereby enters her appearance on behalf of Defendant Gilead Sciences, Inc., only, in the above-captioned matter.

Respectfully submitted,

DYKEMA GOSSETT PLLC

Dated: January 20, 2023

By: */s/ Bonnie Mayfield*

Bonnie Mayfield (P40275)
Attorney for Defendants
39577 Woodward Avenue, Suite 300
Bloomfield Hills, Michigan 48304
Telephone: (248) 203-0700
BMayfield@dykema.com

CERTIFICATE OF SERVICE

I hereby certify that on this 20th day of January, 2023, I electronically filed the foregoing **APPEARANCE** with the Clerk of the Court using the MiFile system which will send notification of such filing to all counsel of record.

/s/ Bonnie Mayfield
Bonnie Mayfield

STATE OF MICHIGAN

IN THE CIRCUIT COURT FOR THE COUNTY OF WASHTENAW

MARK NOWACKI, Legal Guardian and Conservator for DANIEL NOWACKI, and KATHLEEN P. NOWACKI,

Plaintiffs,

vs.

GILEAD SCIENCES, INC. and ST. JOSEPH MERCY CHELSEA, INC. D/B/A ST. JOSEPH MERCY CHELSEA,

Defendants.

Civil Action No. 22-001761-NP

Honorable Carol Kuhnke

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bmayfield@dykema.com

STIPULATED ORDER FOR EXTENSION OF TIME FOR DEFENDANT GILEAD TO RESPOND TO THE COMPLAINT

This matter having come before the Court upon the stipulation of the parties hereto, and the Court being otherwise fully advised in the premises;

IT IS HEREBY ORDERED that the Defendant Gilead Sciences, Inc shall have until February 8, 2023 to answer or otherwise respond to Plaintiffs' Complaint.

SO ORDERED.

DATED: _____

_____
Hon. Carol Kuhnke

SO STIPULATED:

VEN JOHNSON LAW, PLC

By: /s/ *Kanwarpreet S. Khahra*
Vernon R. Johnson (P39219)
Kanwarpreet Singh Khahra (P80253)
Attorneys for Plaintiffs
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DYKEMA GOSSETT PLLC

By: /s/*Bonnie Mayfield*
Bonnie Mayfield (P40275)
Attorneys for Defendant Gilead Sciences, Inc.
38557 Woodward Ave, Ste. 300
Bloomfield Hills, MI 48304
(248) 203-0700
bmayfield@dykema.com

4876-4958-1900.3

Exhibit B

Wolters Kluwer

CT Corporation
Service of Process Notification
01/03/2023
CT Log Number 542955434

Service of Process Transmittal Summary

TO: Legal Department
Trinity Health
20555 VICTOR PARKWAY
LIVONIA, MI 48152

RE: **Process Served in Michigan**

FOR: ST. JOSEPH MERCY CHELSEA, INC. (Domestic State: MI)

ENCLOSED ARE COPIES OF LEGAL PROCESS RECEIVED BY THE STATUTORY AGENT OF THE ABOVE COMPANY AS FOLLOWS:

TITLE OF ACTION:	Re: MARK NOWACKI, as Legal Guardian and Conservator for DANIEL NOWACKI, and KATHLEEN NOWACKI // To: ST. JOSEPH MERCY CHELSEA, INC.
DOCUMENT(S) SERVED:	Letter(s), Summons, Proof, Exhibit(s)
COURT/AGENCY:	22nd Circuit Court - Washtenaw County, MI Case # 22001761NP
NATURE OF ACTION:	Medical Injury - Improper Care and Treatment
PROCESS SERVED ON:	The Corporation Company, Plymouth, MI
DATE/METHOD OF SERVICE:	By Process Server on 01/03/2023 at 16:47
JURISDICTION SERVED:	Michigan
APPEARANCE OR ANSWER DUE:	Within 28 days
ATTORNEY(S)/SENDER(S):	KEN S. KHAHRA JOHNSON LAW, PLC 535 Griswold St., Ste 2600 Detroit, MI 48226 313-324-8301
ACTION ITEMS:	CT has retained the current log, Retain Date: 01/04/2023, Expected Purge Date: 01/09/2023 Image SOP Email Notification, Legal Department sop@trinity-health.org
REGISTERED AGENT CONTACT:	The Corporation Company 40600 Ann Arbor Road E Suite 201 Plymouth, MI 48170 866-331-2303 CentralTeam1@wolterskluwer.com

The information contained in this Transmittal is provided by CT for quick reference only. It does not constitute a legal opinion, and should not otherwise be relied on, as to the nature of action, the amount of damages, the answer date, or any other information contained in the included documents. The recipient(s) of this form is responsible for reviewing and interpreting the

included documents and taking appropriate action, including consulting with its legal and other advisors as necessary. CT disclaims all liability for the information contained in this form, including for any omissions or inaccuracies that may be contained therein.

Ven
JOHNSON LAW, PLC

December 30, 2022

VIA PERSONAL SERVICE and CERTIFIED MAIL
ST. JOSEPH MERCY CHELSEA, INC.
d/b/a ST. JOSEPH MERCY CHELSEA
Resident Agent: The Corporation Company
40600 Ann Arbor Rd, E
Plymouth, MI 48170

Re: Mark Nowacki, as Legal Guardian and Conservator for Daniel Nowacki, et al. v Gilead Sciences, Inc.
Washtenaw County Circuit Court Case No. 22-001761-NP

Dear Mr. Sir/Madam:

We represent the plaintiff in the above-entitled action. Enclosed please find:

1. Summons for Defendant Gilead Sciences, Inc.; and
2. Complaint and Jury Demand.

Please provide these documents to your insurance carrier and conduct yourself accordingly.

Thank you for your attention in this regard.

Yours very truly,

JOHNSON LAW, PLC

Ken S. Khahra

KSK/cts
Enclosures

Approved, SCAO

Original - Court
1st copy - Defendant

2nd copy - Plaintiff
3rd copy - Return

STATE OF MICHIGAN 22nd JUDICIAL DISTRICT JUDICIAL CIRCUIT COUNTY PROBATE	SUMMONS	CASE NO. 22- -NP 22-001761-NP

Court address
101 E Huron St., Ann Arbor, MI 48104

Court telephone no.
734-222-3001

Plaintiff's name(s), address(es), and telephone no(s).
MARK NOWACKI, as Legal Guardian and Conservator for DANIEL NOWACKI, and KATHLEEN NOWACKI,

v

Defendant's name(s), address(es), and telephone no(s).
ST. JOSEPH MERCY CHELSEA, INC., d/b/a
ST. JOSEPH MERCY CHELSEA
Resident Agent: The Corporation Company
40600 Ann Arbor Road East, Ste 201
Plymouth, MI 48170

Plaintiff's attorney, bar no., address, and telephone no.
KEN S. KHAHRA (P80253)
JOHNSON LAW, PLC
535 Griswold St., Ste 2600
Detroit, MI 48226
313-324-8301

Instructions: Check the items below that apply to you and provide any required information. Submit this form to the court clerk along with your complaint and, if necessary, a case inventory addendum (form MC 21). The summons section will be completed by the court clerk.

Domestic Relations Case

☐ There are no pending or resolved cases within the jurisdiction of the family division of the circuit court involving the family or family members of the person(s) who are the subject of the complaint.
☐ There is one or more pending or resolved cases within the jurisdiction of the family division of the circuit court involving the family or family members of the person(s) who are the subject of the complaint. I have separately filed a completed confidential case inventory (form MC 21) listing those cases.
☐ It is unknown if there are pending or resolved cases within the jurisdiction of the family division of the circuit court involving the family or family members of the person(s) who are the subject of the complaint.

Civil Case

☐ This is a business case in which all or part of the action includes a business or commercial dispute under MCL 600.8035.
☐ MDHHS and a contracted health plan may have a right to recover expenses in this case. I certify that notice and a copy of the complaint will be provided to MDHHS and (if applicable) the contracted health plan in accordance with MCL 400.106(4).
☑ There is no other pending or resolved civil action arising out of the same transaction or occurrence as alleged in the complaint.
☐ A civil action between these parties or other parties arising out of the transaction or occurrence alleged in the complaint has been previously filed in ☐ this court, ☐ _____ Court, where it was given case number _____ and assigned to Judge _____.

The action ☐ remains ☐ is no longer pending.

Summons section completed by court clerk. **SUMMONS**

NOTICE TO THE DEFENDANT: In the name of the people of the State of Michigan you are notified:

1. You are being sued.
2. **YOU HAVE 21 DAYS** after receiving this summons and a copy of the complaint to **file a written answer with the court** and serve a copy on the other party **or take other lawful action with the court** (28 days if you were served by mail or you were served outside this state).
3. If you do not answer or take other action within the time allowed, judgment may be entered against you for the relief demanded in the complaint.
4. If you require special accommodations to use the court because of a disability or if you require a foreign language interpreter to help you fully participate in court proceedings, please contact the court immediately to make arrangements.

Issue date	Expiration date*	Court clerk
	03-29-2023	/s/ Kim Plumb December 29, 2022

*This summons is invalid unless served on or before its expiration date. This document must be sealed by the seal of the court.

SUMMONS
Case No. 22- -NP

PROOF OF SERVICE

TO PROCESS SERVER: You are to serve the summons and complaint not later than 91 days from the date of filing or the date of expiration on the order for second summons. You must make and file your return with the court clerk. If you are unable to complete service you must return this original and all copies to the court clerk.

CERTIFICATE / AFFIDAVIT OF SERVICE / NONSERVICE

☐ **OFFICER CERTIFICATE**	OR	☐ **AFFIDAVIT OF PROCESS SERVER**
I certify that I am a sheriff, deputy sheriff, bailiff, appointed court officer, or attorney for a party (MCR 2.104[A][2]), and that: (notarization not required)		Being first duly sworn, I state that I am a legally competent adult, and I am not a party or an officer of a corporate party (MCR 2.103[A]), and that: (notarization required)

☐ I served personally a copy of the summons and complaint,
☐ I served by registered or certified mail (copy of return receipt attached) a copy of the summons and complaint,

together with _____
List all documents served with the summons and complaint

_____ on the defendant(s):

Defendant's name	Complete address(es) of service	Day, date, time

☐ I have personally attempted to serve the summons and complaint, together with any attachments, on the following defendant(s) and have been unable to complete service.

Defendant's name	Complete address(es) of service	Day, date, time

I declare under the penalties of perjury that this proof of service has been examined by me and that its contents are true to the best of my information, knowledge, and belief.

Service fee	Miles traveled	Fee	
$		$	
Incorrect address fee	Miles traveled	Fee	**TOTAL FEE**
$		$	$

_____
Signature

_____
Name (type or print)

_____
Title

Subscribed and sworn to before me on _____ (Date), _____ County, Michigan.

My commission expires: _____ (Date) Signature: _____ (Deputy court clerk/Notary public)

Notary public, State of Michigan, County of _____

ACKNOWLEDGMENT OF SERVICE

I acknowledge that I have received service of the summons and complaint, together with _____ (Attachments)

_____ on _____ (Day, date, time)

_____ on behalf of _____.
Signature

STATE OF MICHIGAN

IN THE CIRCUIT COURT FOR THE COUNTY OF WASHTENAW

MARK NOWACKI, as Legal Guardian and Conservator
for DANIEL NOWACKI, and KATHLEEN P. NOWACKI,

Plaintiffs,

22-001761-NP

Case No.: 22- -NP
Hon. JUDGE CAROL KUHNKE

vs

GILEAD SCIENCES, INC., and
ST. JOSEPH MERCY CHELSEA, INC., *d/b/a*
ST. JOSEPH MERCY CHELSEA,

Defendants.
_____/

KANWARPREET S. KHAHRA (P80253)
VEN R. JOHNSON (P39219)
JOHNSON LAW, PLC
Attorneys for Plaintiff
Buhl Building
535 Griswold Street, Suite 2632
Detroit, Michigan 48226
(313) 324-8300
kkhahra@venjohnsonlaw.com
vjohnson@venjohnsonlaw.com
_____/

The undersigned hereby certifies that there is no other pending or resolved civil action between the same parties arising out of the transaction or occurrence alleged in the complaint.

/s/ Kanwarpreet S. Khahra
Kanwarpreet S. Khahra

COMPLAINT AND DEMAND FOR JURY TRIAL

NOW COMES, the Plaintiffs, MARK NOWACKI, as Legal Guardian and Conservator for DANIEL NOWACKI, and KATHLEEN P. NOWACKI, by and through his attorneys, JOHNSON LAW, PLC, for his complaint and cause of action against Defendants, GILEAD SCIENCES INC., and ST. JOSEPH MERCY CHELSEA, INC., states the following:

1. The acts or omissions which form the basis for this complaint occurred in the County of Washtenaw, State of Michigan.

2. The amount in controversy is in excess of TWENTY-FIVE THOUSAND ($25,000) dollars exclusive of costs, interest, and attorney fee.

3. Venue is proper pursuant to MCL 600.1629.

4. At all times pertinent to the complaint, Plaintiff, MARK NOWACKI, as Legal Guardian and Conservator for DANIEL NOWACKI (hereinafter "Dan") was a resident of Onsted, County of Lenawee, State of Michigan.

5. At all times pertinent to the complaint, Plaintiff, KATHLEEN P. NOWACKI, was the lawfully wedded wife of DANIEL NOWACKI and resided with him in Michigan.

6. At all times pertinent to the complaint, Defendant, GILEAD SCIENCES INC., (hereinafter "GILEAD") was a domestic corporation incorporated under the laws of Delaware, doing continuous and systemic business in the State of Michigan. The resident agent for GILEAD in Michigan is: THE CORPORATION COMPANY, which is located at 40600 Ann Arbor Road East, Suite 201, Plymouth, Michigan.

7. At all times pertinent to the complaint, Defendant, ST. JOSEPH MERCY CHELSEA, INC., (hereinafter "St. Joseph Mercy hospital") was a domestic corporation incorporated under the laws of Michigan, doing continuous and systemic business in the State of Michigan. The resident agent of ST. JOSEPH MERCY is: THE CORPORATION COMPANY, which is located at 40600 Ann Arbor Road East, Suite 201, Plymouth, Michigan.

8. In paragraphs 9-20 as set forth below, the Plaintiffs makes reference to the statements contained in the medical records of various health care providers of DANIEL NOWACKI. The recitation of these factual statements should not be interpreted as an admission

by Plaintiffs as to the factual authenticity or truthfulness of these statements. The statements are set forth below to provide context as to the allegations as described below.

STATEMENT OF FACTS

9. On November 9, 2021, Daniel Nowacki (83) presented to St. Joseph Mercy hospital in Chelsea, MI, with complaints of fatigue for past three (3) days, cough, some shortness of breath, and decreased appetite.

10. That same day, Dan was diagnosed with COVID-19 and received monoclonal antibodies and was discharged home.

11. On November 10, 2021, Dan returned to the emergency department at St. Joseph Mercy via EMS because of worsening fatigue and shortness of breath. EMS noted that Dan was hypoxic with his SPO2 at 86% on room air.

12. A chest x-ray performed at the hospital revealed mild to moderate airspace disease throughout the bilateral lungs and possible trace of pleural effusion.

13. On November 10, 2021, Dan received IV Decadron and Remdesivir (also known as Veklury) to treat his hypoxia.

14. On November 11, 2021, Dan received another dose of IV Remdesivir.

15. After receiving Remdesivir, Dan's experienced a stroke which was confirmed by CTA Head/Neck on November 19, 2021, and showed, *inter alia*, a complete occlusion of the right internal carotid artery.

16. On November 20, 2021, Dan underwent an MRI Brain to rule out Dural Venous Thrombosis which revealed,

a. Moderate sized region of acute infarction involves right cerebral hemisphere, predominantly affecting mid-posterior right frontal and right parietal lobes. This region of restricted water diffusion is somewhat oriented in a linear parasagittal configuration which may indicate "watershed-type" ischemia.

b. Brain volume/intracranial atrophy compared to the Head CT on 11/18/2021.

c. More focal encephalomalacia involving right frontal lobe, probability due to prior infarction.

d. Scattered foci of T2 hyperintensity within cerebral hemispheric white matter and adjacent basal ganglia not associated with mass effect, contrast enhancement or restricted water diffusion probably due to subacute/chronic ischemia.

e. Absence of anticipated flow-void from upper cervical and proximal intracranial right internal carotid artery suggesting altered flow. The findings are consistent with previously diagnosed right internal carotid artery occlusion.

17. Dan was diagnosed with cerebral infarction due to vascular occlusion and discharged on November 24, 2021, to a skilled nursing facility.

18. Over the next several days, Dan started developing hematomas and reported swelling on his face, thighs, arms and was admitted to Henry Ford hospital. The cause of these hematomas and swelling remained a mystery to Dan's treating physicians.

19. On approximately December 14, 2021, Dan suffered another stroke in the posterior frontal, parietal, and occipital region which has left him bedridden.

20. On April 6, 2022, Mark Nowacki received a letter from St. Joseph Mercy hospital (Chelsea) confirming that Dan had received five doses of Remdesivir during his November 10, 2022, admission which were subject to Gilead nationwide recall of Remdesivir due to presence of foreign body – glass particles in the drug. **(Letter, Exhibit 1).**

21. The recall dated December 3, 2021, pertained to two lots (#2141001-1A and 2141002-1A) totaling approximately 55,000 vials of Remdesivir. **(Recall, Exhibit 2).** The recall was published on FDA website and contained the following risk statement:

> The administration of an injectable that contains glass particulates may result in local irritation or swelling in response to the foreign material. If the glass particulate reaches the blood vessels it can travel to various organs and block blood vessels in the heart, lungs,

> or brain which can cause stroke and even lead to death. To date, Gilead Sciences Inc., has not received any reports of adverse events related to this recall.

22. While Gilead indicated in the recall that it had not received any reports of adverse events, the company acknowledged in the recall notification that it had received a customer complaint, confirmed by company's investigation, which led to the discovery of glass particles.

23. The recall further stated that Gilead is notifying its distributors and customers via UPS next day air mail to hospital pharmacies and is facilitating the return of any remaining vials from the affected lots. Hospitals that have Veklury [Remdesivir] which is being recalled should stop using the affected lots and return the product vials per the instructions.

24. Unfortunately, neither Dan nor his family was made aware that Dan had received Remdesivir that contained glass particles (foreign body) which was responsible for causing his stroke until after a letter was received from St. Joseph Mercy on or about April 6, 2022. As such, Dan's subsequent treating physicians including staff at Henry Ford were unaware of this fact and could not appropriately deal with Dan's medical condition.

25. As a result of these glass particles, Dan has suffered two strokes and has had a leg amputated and is left bedridden for rest of his life thereby requiring 24/7 care.

REMDESIVIR [VEKLURY] BACKGROUND

26. Remdesivir was the first experimental drug to receive FDA approval for treatment against COVID-19 in certain patient population.

27. The drug was given to President Donald Trump when he contracted COVID-19.

28. The FDA approved the drug on October 22, 2020, on a fast-track basis pursuant to Gilead's representations that the drug was safe and effective against COVID-19 as part of its submissions on August 7, 2020 (NDA 214787).

29. The average cost of Remdesivir as set by Gilead ranged between $390-$520 per vial or $2,340-$3,120 for a full five-day course of treatment.

30. At the time that FDA approved the drug, there was no indication of glass particles (foreign body) being present in the drug composition.

31. Upon information and belief, Gilead did not disclose and/or misrepresented to the FDA about the possibility of glass particles (foreign body) being present in the drug composition and/or some batches thereof which could cause serious adverse events such as, stroke and/or death.

32. Gilead represented to FDA that its drug quality was appropriate and the proposed facilities for drug manufacturing had satisfactory Current Good Manufacturing Practices (cGMP).

33. The FDA's decision to approve the drug was based on results of three randomized clinical trials funded and/or performed by Gilead that showed that Remdesivir could reduce mortality and improve outcomes.

34. The FDA approval came within two weeks after World Health Organization (WHO) rejected the use of Remdesivir based on its solidarity trial conducted in approximately 405 hospitals in 30 countries where it was determined that Remdesivir did not improve mortality and outcome in patients suffering from COVID-19. In fact, WHO raised concerns regarding Remdesivir causing more harm based on complaints of liver and kidney problems in patients who received the drug.

35. The FDA typically convenes an independent advisory committee to review drugs prior to approval if there are questions regarding the drug's efficacy or safety but did not so for Remdesivir despite strong public contention that an independent committee be impaneled to review the drug's efficacy. **(Public Citizen Letter, Exhibit 3).** The agency instead stated that it

was not necessary because Gilead's application for approval did not raise significant safety or efficacy issues. **(FDA response, Exhibit 4).**

36. Prior to receiving FDA approval, Remdesivir had received an emergency-use authorization in May 2020 after preliminary data from governmental trial, run by NIH's National Institute of Allergy and Infectious Diseases, showed that Remdesivir cut the length of hospital stays.

37. Upon information and belief, and based on information currently available in the public domain, several panel members of NIH that served as research support and/or on the advisory board had financial ties with Gilead. **(Panel Roster/Financial Disclosure, Exhibit 5).**

38. Upon information and belief, had FDA known about the potential for Remdesivir to contain glass particles (foreign body) prior to the drug being introduced in the stream of commerce, it would have withheld and/or withdrawn its approval until such time that Gilead took appropriate measure to eliminate the risk of glass particles (foreign body) being present in the drug.

39. The Remdesivir drug administered to Dan during his admission to St. Joseph Mercy hospital was not in accordance with Gilead's FDA approval for the drug in terms of its manufacturing quality and/or labeling.

COUNT I – BREACH OF IMPLIED WARRANTY (GILEAD)

The Plaintiffs restates, realleges, and incorporates by reference each and every paragraph set forth above, as though fully set forth herein, and further states, in the alternative, the following:

40. At all times pertinent to this complaint, the Remdesivir drug administered to Dan contained glass particles (foreign body) and was not reasonably fit for its intended, anticipated, or reasonably foreseeable use at the time it left Gilead's control.

41. At all times pertinent to this complaint, Gilead acknowledged in the recall that the glass particles were known to cause adverse events such as, stroke and/or death if they became lodged in a blood vessel.

42. At all times pertinent to this complaint, the U.S. Food and Drug Administration (FDA) did not approve Remdesivir with presence of glass particles (foreign body) when the drug received its questionable FDA approval.

43. At all times pertinent to this complaint, Gilead did not inform FDA prior to introducing Remdesivir into the stream of commerce about the possibility of glass particles (foreign body) being present in the drug and/or some batches thereof which would have undermined its safety and efficacy and caused FDA to withhold and/or withdraw its approval.

44. At all times pertinent to this complaint, Gilead recalled the affected lots containing glass particles with the knowledge of FDA clearly indicating that FDA did not approve Remdesivir with presence of glass particles (foreign body) given its potential adverse effects.

45. At all times pertinent to this complaint, the Remdesivir drug administered to Dan during his admission to St. Joseph Mercy hospital was not in accordance Gilead's FDA approval for the drug in terms of its manufacturing quality and/or labeling as it contained glass particles (foreign body).

46. At all times pertinent to this complaint, Dan and/or others similarly situated were entitled to rely upon the implied warranty of fitness and suitability, which attended the design, manufacture, distribution, labeling, and sale of the Remdesivir drug.

47. At all times pertinent to this complaint, Dan suffered serious injuries as a result of his reliance on the implied warranty of fitness and suitability, which attended the design, manufacture, distribution, labeling, and sale of Remdesivir drug.

48. As a direct and proximate result of the breach of implied warranty, Dan suffered the following injuries and damages:

a. Stroke and associated sequelae.

b. Leg amputation.

c. Pain and suffering, past, present, and future;

d. Disability and disfigurement, past, present, and future;

e. Emotional distress and anxiety, past, present, and future;

f. Denial of social pleasures and enjoyments;

g. Medical expenses, past, present, and future;

h. Loss of wages and earnings capacity, past, present, and future;

i. Attendant care and replacement services, past, present, and future;

j. Other injuries and damages to be determined through the course of discovery and described in Dan's medical records.

WHEREFORE, the Plaintiffs respectfully requests that this Honorable Court enter a judgment against Gilead in any amount in excess of TWENTY-FIVE THOUSAND ($25,000) DOLLARS, together with interest, costs, and attorney fees, to which the Plaintiff is deemed to be entitled.

COUNT II – BREACH OF EXPRESS WARRANTY (GILEAD)

The Plaintiffs restates, realleges, and incorporates by reference each and every paragraph set forth above, as though fully set forth herein, and further states, in the alternative, the following:

49. At all times pertinent to this complaint, Gilead expressly warranted, through its marketing, advertising, distributors, and sales representatives that Remdesivir was of merchantable quality and fit for the ordinary purposes and uses for which it was sold.

50. These statements made constitute express warranties regarding the Remdesivir drug.

51. At all times pertinent to this complaint, Gilead breached these express warranties by designing, labeling, manufacturing, and selling defective and unreasonably dangerous Remdesivir drug containing glass particles (foreign body) that was neither of merchantable quality nor fit for the ordinary purposes for which it was sold, presenting an unreasonable risk of injury to patients, including Dan, during foreseeable use.

52. Notwithstanding those statements, the Remdesivir drug containing glass particles (foreign particles) was sold in breach of the attendant express warranties.

53. Gilead knew, or should have known, at the time Remdesivir drug containing glass particles (foreign body) left its control that it was defective and dangerous and there was a substantial likelihood that the glass particles would cause serious injuries which form the basis for this action.

54. At all times pertinent to this complaint, Dan and/or others similarly situated were entitled to rely upon and did rely upon the express warranties which attended the sale of Remdesivir drug.

55. Dan suffered serious injuries as a result of his and St. Joseph Mercy hospital's reliance on the express warranties which attended the sale of defective Remdesivir drug containing glass particles (foreign body).

56. As a direct and proximate result of the breach of express warranties, Dan suffered the following injuries and damages:

a. Stroke and associated sequelae.

b. Leg amputation.

c. Pain and suffering, past, present, and future;

d. Disability and disfigurement, past, present, and future;

e. Emotional distress and anxiety, past, present, and future;

f. Denial of social pleasures and enjoyments;

g. Medical expenses, past, present, and future;

h. Loss of wages and earnings capacity, past, present, and future;

i. Attendant care and replacement services, past, present, and future;

j. Other injuries and damages to be determined through the course of discovery and described in Dan's medical records.

WHEREFORE, the Plaintiffs respectfully requests that this Honorable Court enter a judgment against Gilead in any amount in excess of TWENTY-FIVE THOUSAND ($25,000) DOLLARS, together with interest, costs, and attorney fees, to which the Plaintiff is deemed to be entitled.

COUNT III – NEGLIGENCE (GILEAD)

The Plaintiffs restates, realleges, and incorporates by reference each and every paragraph set forth above, as though fully set forth herein, and further states, in the alternative, the following:

57. At all times pertinent to this complaint, Gilead owed the general public including, Dan a duty to appropriately design, label, manufacture, assemble, inspect, test, and market Remdesivir drug free from glass particles (foreign body).

58. Notwithstanding the said obligation, and in breach thereof, Gilead was negligent in design, manufacture, assembly, testing, marketing, labeling, packaging, inspecting, and sale of the Remdesivir drug at the time it left Gilead's control, in the manner set forth below:

a. Failed to test and/or inspect the drug for presence of glass particles before placing it into the stream of commerce.

b. Failed to have a manufacturing and/or assembly process that would eliminate the possibility of glass particles from entering the drug composition.

c. Failed to include appropriate warning label on the drug apprising the medical providers and/or ultimate users of the possibility of presence of glass particles (foreign body) in the drug and their adverse effects on health.

d. Failed to disclose and/or misrepresented to FDA about the possibility of glass particles (foreign body) being present in the drug composition during manufacturing and/or assembly process which would have undermined its safety and efficacy and would have caused FDA to withhold and/or withdraw its approval.

e. Improperly obtaining FDA approval in the first place by submitting results of self-funded randomized control trials, in part, overseen by NIH where several members of NIH had financial ties to Gilead.

f. Others acts or omissions that may be revealed through discovery.

59. At all times pertinent to this complaint, Gilead knew or should have known that the Remdesivir drug containing glass particles (foreign body) was defective at the time it left its control and there was a substantial likelihood that the glass particles would cause serious injuries which form the basis for this action.

60. As a direct and proximate result of the aforementioned negligent acts and/or omissions, Dan suffered the following injuries and damages:

a. Stroke and associated sequelae.

b. Leg amputation.

c. Pain and suffering, past, present, and future;

d. Disability and disfigurement, past, present, and future;

e. Emotional distress and anxiety, past, present, and future;

f. Denial of social pleasures and enjoyments;

g. Medical expenses, past, present, and future;

h. Loss of wages and earnings capacity, past, present, and future;

i. Attendant care and replacement services, past, present, and future;

j. Other injuries and damages to be determined through the course of discovery and described in Dan's medical records.

WHEREFORE, the Plaintiffs respectfully requests that this Honorable Court enter a judgment against Gilead in any amount in excess of TWENTY-FIVE THOUSAND ($25,000) DOLLARS, together with interest, costs, and attorney fees, to which the Plaintiff is deemed to be entitled.

COUNT IV – GROSS NEGLIGENCE (GILEAD)

The Plaintiffs restates, realleges, and incorporates by reference each and every paragraph set forth above, as though fully set forth herein, and further states, in the alternative, the following:

61. At all times pertinent to this complaint, Gilead owed the general public including, Dan a duty to appropriately design, label, manufacture, assemble, inspect, test, and market Remdesivir drug free from glass particles (foreign body).

62. At all times pertinent to this complaint, Gilead was grossly negligent and acted in wanton disregard for the safety of the consumers of Remdesivir including Dan and his medical providers, out of concern for its pecuniary benefit.

63. At all times pertinent to this complaint, Gilead knew or should have known that the Remdesivir drug containing glass particles (foreign body) was defective and there was a substantial likelihood that the glass particles would cause serious injuries which form the basis for this action.

64. At all times pertinent to this complaint, Gilead introduced Remdesivir drug containing glass particles (foreign body) into the stream of commerce knowing fully well that the glass particles could cause serious injuries such as, stroke and/or even death.

65. The above-cited conduct was so reckless so as to demonstrate a substantial lack of concern for whether an injury resulted to consumers such as, Dan from consuming Remdesivir with glass particles (foreign body).

66. As a direct and proximate result of the aforementioned grossly negligent acts, Dan suffered the following injuries and damages:

a. Stroke and associated sequelae.

b. Leg amputation.

c. Pain and suffering, past, present, and future;

d. Disability and disfigurement, past, present, and future;

e. Emotional distress and anxiety, past, present, and future;

f. Denial of social pleasures and enjoyments;

g. Medical expenses, past, present, and future;

h. Loss of wages and earnings capacity, past, present, and future;

i. Attendant care and replacement services, past, present, and future;

j. Other injuries and damages to be determined through the course of discovery and described in Dan's medical records.

WHEREFORE, the Plaintiffs respectfully requests that this Honorable Court enter a judgment against Gilead in any amount in excess of TWENTY-FIVE THOUSAND ($25,000) DOLLARS, together with interest, costs, and attorney fees, to which the Plaintiff is deemed to be entitled.

COUNT V – INTENTIONAL MISREPRESENTATION (GILEAD)

The Plaintiffs restates, realleges, and incorporates by reference each and every paragraph set forth above, as though fully set forth herein, and further states, in the alternative, the following:

67. At all times pertinent to this complaint, Gilead owed the general public including, Dan a duty to appropriately design, label, manufacture, assemble, inspect, test, and market Remdesivir drug free from glass particles (foreign body).

68. At all times pertinent to this complaint, Gilead through its application for fast-track FDA approval represented to the FDA that Remdesivir was safe and effective against COVID-19.

69. At all times pertinent to this complaint, Gilead through its application for fast-track FDA approval represented to the FDA that Remdesivir drug composition and manufacturing processes were appropriate.

70. At all times pertinent to this complaint, Gilead through its application for fast-track FDA approval represented to the FDA that the proposed facilities for Remdesivir manufacturing were satisfactory and in accordance with Current Good Manufacturing Practices (cGMP).

71. At all times pertinent to this complaint, Gilead knew or had reason to know that its representations were not accurate and that there was a possibility of glass particles (foreign body) being present in Remdesivir due to its manufacturing and/or assembly process which would undermine its safety and efficacy and, therefore, would not receive FDA approval.

72. At all times pertinent to the complaint, Gilead had a duty to disclose the possibility of glass particles (foreign body) being present in Remdesivir and breached said duty when it failed to make any reference in its submissions to FDA for drug approval clearly for its pecuniary benefit.

73. As a direct and proximate result of the aforementioned acts and/or omissions, Dan suffered the following injuries and damages:

a. Stroke and associated sequelae.

b. Leg amputation.

c. Pain and suffering, past, present, and future;

d. Disability and disfigurement, past, present, and future;

e. Emotional distress and anxiety, past, present, and future;

f. Denial of social pleasures and enjoyments;

g. Medical expenses, past, present, and future;

h. Loss of wages and earnings capacity, past, present, and future;

i. Attendant care and replacement services, past, present, and future;

j. Other injuries and damages to be determined through the course of discovery and described in Dan's medical records.

WHEREFORE, the Plaintiffs respectfully requests that this Honorable Court enter a judgment against Gilead in any amount in excess of TWENTY-FIVE THOUSAND ($25,000) DOLLARS, together with interest, costs, and attorney fees, to which the Plaintiff is deemed to be entitled.

COUNT VI – NEGLIGENCE (ST. JOSEPH MERCY HOSPITAL)

The Plaintiffs restates, realleges, and incorporates by reference each and every paragraph set forth above, as though fully set forth herein, and further states, in the alternative, the following:

74. At all times pertinent to this complaint, St. Joseph Mercy hospital through its president, chief medical officer, hospital administrator, and/or other employees, agents, and/or representatives owed Dan a duty to expeditiously warn or inform him and/or his family members that Dan had received Remdesivir drug containing glass particles (foreign body) so that his subsequent treating physicians could provide appropriate treatment.

75. Notwithstanding the said obligation, and in breach thereof, St. Joseph Mercy hospital through its president, chief medical officer, hospital administrator, and/or other employees, agents, and/or representatives was negligent in the manner set forth below:

a. Failed to immediately warn or inform Dan and/or his family members after receiving Gilead's recall notification dated December 3, 2020, that Dan was administered the affected Remdesivir drug (Lot #2141001-1A) containing glass particles (foreign body) which was responsible for his stroke.

b. Failed to immediately warn or inform Dan and/or family members as indicated by Gilead in the recall notification to seek immediate medical help relating to adverse effects from administration of Remdesivir drug containing glass particles (foreign body).

c. Other acts or omissions that may be revealed through discovery.

76. As a direct and proximate result of the aforementioned negligent acts and/or omissions, Dan suffered the following injuries and damages:

a. Second stroke on or about December 14, 2021, and associated sequelae.

b. Leg amputation.

c. Pain and suffering, past, present, and future;

d. Disability and disfigurement, past, present, and future;

e. Emotional distress and anxiety, past, present, and future;

f. Denial of social pleasures and enjoyments;

g. Medical expenses, past, present, and future;

h. Loss of wages and earnings capacity, past, present, and future;

i. Attendant care and replacement services, past, present, and future;

j. Other injuries and damages to be determined through the course of discovery and described in Dan's medical records.

WHEREFORE, the Plaintiffs respectfully requests that this Honorable Court enter a judgment against St. Joseph Mercy hospital in any amount in excess of TWENTY-FIVE THOUSAND ($25,000) DOLLARS, together with interest, costs, and attorney fees, to which the Plaintiff is deemed to be entitled.

COUNT VII – GROSS NEGLIGENCE (ST. JOSEPH MERCY HOSPITAL)

The Plaintiffs restates, realleges, and incorporates by reference each and every paragraph set forth above, as though fully set forth herein, and further states, in the alternative, the following:

77. At all times pertinent to this complaint, St. Joseph Mercy hospital through its president, chief medical officer, hospital administrator, and/or other employees, agents, and/or representatives owed Dan a duty to expeditiously warn or inform him and/or his family members that Dan had received Remdesivir drug containing glass particles (foreign body) so that his subsequent treating physicians could provide appropriate treatment.

78. At all times pertinent to this complaint, St. Joseph Mercy hospital was grossly negligent and acted in wanton disregard for the safety of the consumers of Remdesivir including Dan by failing to immediately notify him about the fact that he had received several doses of Remdesivir containing glass particles (foreign body) which was responsible for his stroke.

79. The above-cited conduct was so reckless so as to demonstrate a substantial lack of concern for whether an injury resulted to consumers such as, Dan from consuming Remdesivir with glass particles (foreign body).

80. As a direct and proximate result of the aforementioned grossly negligent acts, Dan suffered the following injuries and damages:

a. Stroke and associated sequelae.

b. Leg amputation.

c. Pain and suffering, past, present, and future;

d. Disability and disfigurement, past, present, and future;

e. Emotional distress and anxiety, past, present, and future;

f. Denial of social pleasures and enjoyments;

g. Medical expenses, past, present, and future;

h. Loss of wages and earnings capacity, past, present, and future;

i. Attendant care and replacement services, past, present, and future;

j. Other injuries and damages to be determined through the course of discovery and described in Dan's medical records.

WHEREFORE, the Plaintiffs respectfully requests that this Honorable Court enter a judgment against St. Joseph Mercy hospital in any amount in excess of TWENTY-FIVE THOUSAND ($25,000) DOLLARS, together with interest, costs, and attorney fees, to which the Plaintiff is deemed to be entitled.

COUNT VIII – LOSS OF CONSORTIUM (KATHLEEN P. NOWACKI)

The Plaintiffs restates, realleges, and incorporates by reference each and every paragraph set forth above, as though fully set forth herein, and further states, in the alternative, the following:

81. At all times pertinent to this complaint, Kathleen P. Nowacki, was the lawfully wedded wife of Daniel Nowacki.

82. As a direct and proximate result of injuries suffered by Dan because of the glass particles (foreign body) in the Remdesivir drug, Kathleen has suffered and will continue to suffer the loss of consortium including, the loss of her husband's society, companionship, and household services.

WHEREFORE, the Plaintiffs respectfully requests that this Honorable Court enter a judgment against the Defendants in any amount in excess of TWENTY-FIVE THOUSAND ($25,000) DOLLARS, together with interest, costs, and attorney fees, to which the Plaintiff is deemed to be entitled.

Respectfully submitted,

JOHNSON LAW, PLC

By: */s/ Kanwarpreet S. Khahra*

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Dated: December 28, 2022

EXHIBIT 1

ST. JOSEPH MERCY
CHELSEA

775 South Main Street
Chelsea, MI 48118
734-593-6000

April 6th, 2022

Mr. Mark Nowacki
29 Twin Lakes Dr.
Onsted, MI 49265

RE: Administration of Recalled Remdesivir to Mr. Daniel Nowacki

Dear Mr. Mark Nowacki,

Thank you for your inquiry regarding whether or not your father, Mr. Daniel Nowacki received any of the drug Remdesivir which is subject to the manufacturer Gilead's voluntary recall. We apologize for the delay in responding as we had to research this further in order to verify the information. Our records indicate Mr. Daniel Nowacki was in the hospital between November 10, 2021 and November 24, 2021 and did receive the medication that is subject to the recall. The recall announcement was dated December 3, 2021 and when Mr. Daniel Nowacki was given Remdesivir we were not yet aware of the recall.

Two of the five doses in the course of treatment received by Mr. Daniel Nowacki involved the recalled lot #'s. Those doses were administered on November 10th, 2021 (lot #2141001-1a) and November 11th, 2021 (lot #2141001-1a). The other doses with corresponding lot #'s were as follows; November 12th, 2021 (lot #27015BFA), November 13th, 2021 (lot #27015BFA) and November 14th, 2021 (lot #27015BFA).

If you have any questions regarding health concerns, we recommend you follow up with your primary care provider. Additionally, we are including Gilead's recall announcement for your information.

Sincerely,

Jennifer Rodriguez, PharmD

Jennifer Rodriguez, PharmD
Inpatient Pharmacy Manager
St. Joseph Mercy Chelsea

Enclosure

EXHIBIT
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A

EXHIBIT 2

COMPANY ANNOUNCEMENT

Gilead Issues A Voluntary Nationwide Recall of Two Lots of Veklury® (Remdesivir) Due to Presence of Glass Particulates

This recall has been completed and FDA has terminated this recall.

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

Read Announcement | View Product Photos

Summary

Company Announcement Date:

December 03, 2021

FDA Publish Date:

December 03, 2021

Product Type:

Drugs

Reason for Announcement:

Presence of glass particulates

Company Name:

Gilead Sciences Inc.

Brand Name:

Gilead

Product Description:

Veklury® (remdesivir 100 mg for injection)

Company Announcement

Foster City, CA, Gilead Sciences Inc. (Nasdaq: GILD) today announced it is voluntarily recalling two lots of Veklury® (remdesivir 100 mg for injection) to the user level. Gilead Sciences Inc. received a customer complaint, confirmed by the firm's investigation, of the presence of glass

particulates.

Risk Statement: The administration of an injectable product that contains glass particulates may result in local irritation or swelling in response to the foreign material. If the glass particulate reaches the blood vessels it can travel to various organs and block blood vessels in the heart, lungs or brain which can cause stroke and even lead to death. To date, Gilead Sciences Inc. has not received any reports of adverse events related to this recall.

Veklury is indicated for the treatment of adults and pediatric patients ≥ 12 years old and weighing ≥40 kg requiring hospitalization for COVID-19. The lyophilized form of Veklury (remdesivir 100 mg for injection) is distributed in single dose clear glass vials in powder form and reconstituted at the site of use. Veklury lots 2141001-1A and 2141002-1A were distributed nationwide in the United States, beginning October 2021. NDC, lot, expiration date and distribution dates can be found in the table below.

Product Description	NDC	Lot #	Expiration Date	Distribution date to wholesalers
Veklury® (remdesivir 100mg for injection)	61958-2901-02	2141001-1A 2141002-1A	01/2024 01/2024	10/25/21-10/26/2021 10/26/21-11/02/2021

Gilead is notifying its distributors and customers via UPS next day air mail to hospital pharmacies and is facilitating the return of any remaining vials from the affected lots. Hospitals that have Veklury which is being recalled should stop using the affected lots and return the product vials per the instructions.

Consumers with questions regarding this recall can contact Gilead Medical Information at 1-866-633-4474 Monday to Friday 6am - 4pm PST or through their website at www.askgileadmedical.com. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda)
- Regular Mail or Fax: Download form (/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting) or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

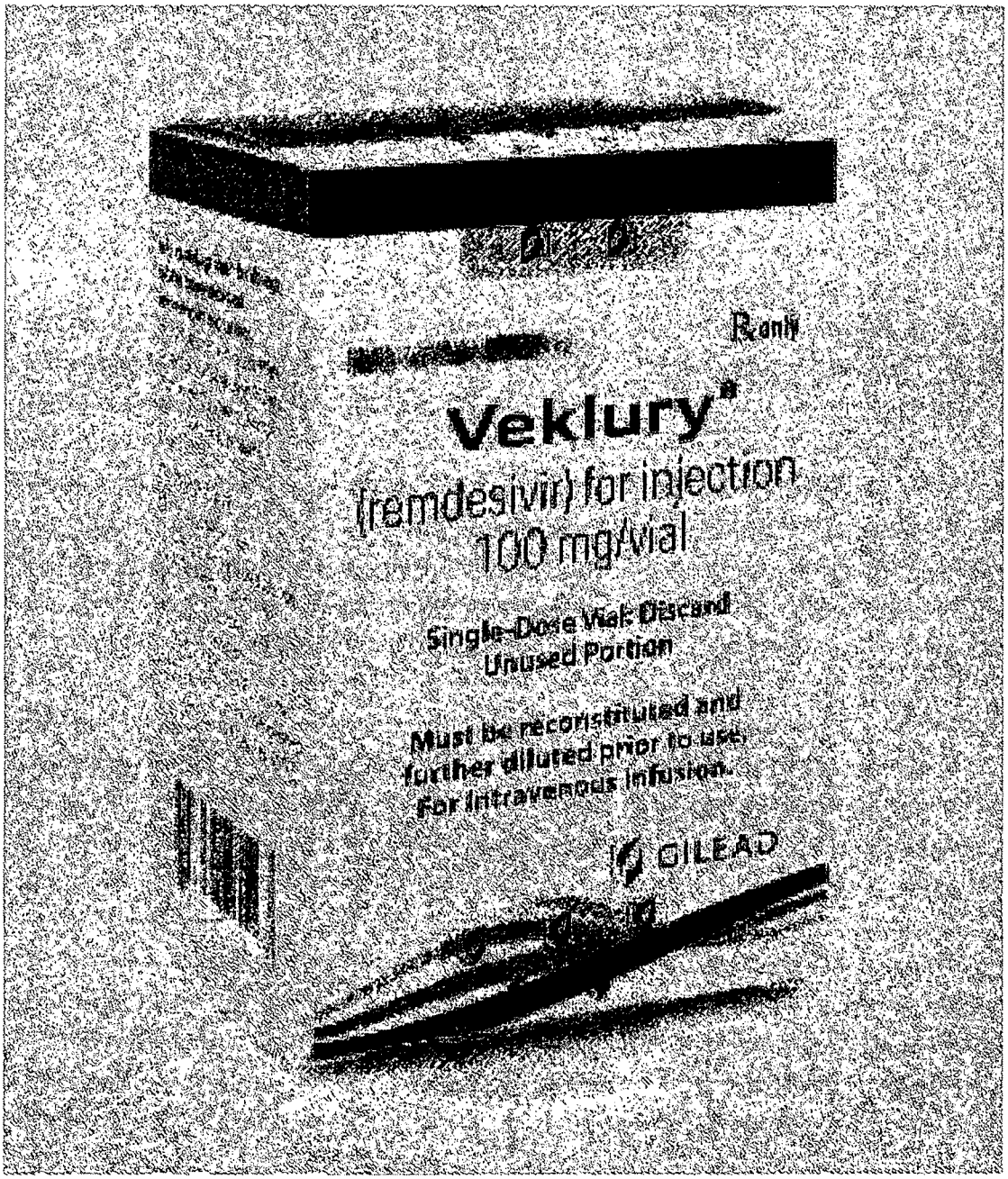
Company Contact Information

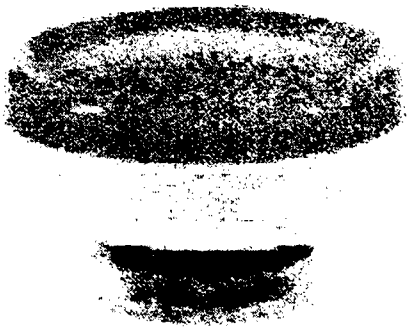
Consumers:

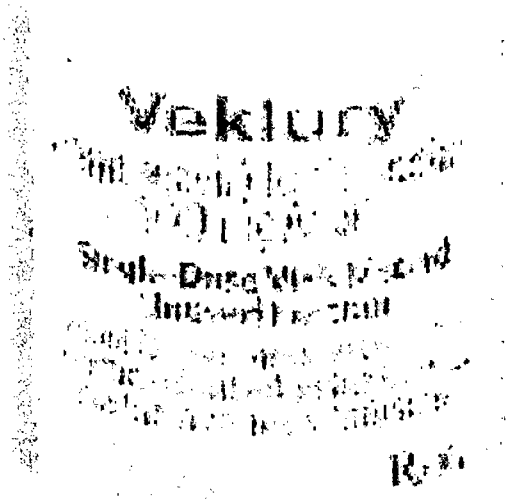
Gilead Medical Information

1-866-633-4474

Product Photos






Veklury

More Recalls, Market Withdrawals, & Safety Alerts (/safety/recalls-market-withdrawals-safety-alerts)

Exhibit C

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

MARK NOWACKI, as Legal Guardian and Conservator for DANIEL NOWACKI, and KATHLEEN P. NOWACKI,

Plaintiffs,

CASE NO.: _____
CONSENT TO REMOVAL

GILEAD SCIENCES, INC. and ST. JOSEPH MERCY CHELSEA, INC., d/b/a ST. JOSEPH MERCY CHELSEA,

Defendants.

(Removed from the State of Michigan, County of Washtenaw, , Circuit Court, Case No.22-001761-NP)

CONSENT TO REMOVAL

Defendant St. Joseph Mercy Chelsea, Inc., d/b/a St. Joseph Mercy Chelsea, by its undersigned counsel, with full reservation of any and all rights and defenses, including rights and defenses based upon defects in compliance with MCL 600.2912b and MCL 600.2912d, hereby consents to the removal of the case captioned Mark Nowacki, as Legal Guardian and Conservator for Danile Nowacki, and Kathleen P. Nowacki from the Circuit Court for the County of Washtenaw, State of Michigan (Case No. 22-001761-NP), to the United States District Court for the Eastern District of Michigan, Southern Division.

Dated this 31st day of January, 2023.

David R. Nauts (P42989),
Its Attorney