No. 18-

IN THE

Supreme Court of the United States

W. SCOTT HARKONEN, M.D.,
Petitioner,

v.

UNITED STATES OF AMERICA,
Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether a writ of error coram nobis should issue for a petitioner who presents "compelling" new evidence that establishes his actual innocence of the crime of conviction.

TABLE OF CONTENTS

TABLE OF CONTENTS—Continued

TABLE OF AUTHORITIES

CASES

TABLE OF AUTHORITIES—Continued

TABLE OF AUTHORITIES—Continued

DOCKETED CASES

STATUTES, RULES, AND REGULATIONS

OTHER AUTHORITIES

TABLE OF AUTHORITIES—Continued

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Dr. Scott Harkonen respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Ninth Circuit in this case.

OPINIONS BELOW

The opinion of the Ninth Circuit affirming the denial of Dr. Harkonen's petition for a writ of error coram nobis (App. 1a-4a) is unpublished but is available at 705 F. App'x 606. The Ninth Circuit's order denying the petition for rehearing (App. 29a-30a) is unreported. The opinion of the district court denying Dr. Harkonen's coram nobis petition (App. 5a-27a) is unpublished but is available at 2015 WL 4999698.

JURISDICTION

The Ninth Circuit entered judgment on December 4, 2017, and denied a timely rehearing petition on June 1, 2018. App. 1a, 29a-30a. On July 30, 2018, Justice Kennedy extended the time to file a petition for a writ of certiorari to October 1, 2018. No. 18A107. This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

INTRODUCTION

W. Scott Harkonen, M.D. is an experienced medical researcher. In 2009, he was convicted of wire fraud, based on statistical evidence the government claimed showed a press release he issued was false. In 2016, the American Statistical Association formally disavowed the statistical theory at the heart of the prosecution. The court below found that the evidence that Dr. Harkonen is innocent was "compelling." App. 2a. But the court declined to vacate Dr. Harkonen's conviction, holding that *more* than actual innocence was required before a writ of coram nobis vacating the conviction could be issued. This holding conflicts with the holdings of three other circuits (the Sixth, Eighth, and Tenth) that actual innocence itself *is* a basis for coram nobis relief. The Court should grant review to address the circuit split on this important question, and should hold that at least where advances in science establish innocence, coram nobis relief is appropriate.

The press release at issue reported the results of a clinical trial. The trial was designed to evaluate the safety and efficacy of a biologic drug, Actimmune, to treat a rare, progressive invariably fatal lung disease known as idiopathic pulmonary fibrosis (IPF).

The trial showed something compelling: There was a 40% reduction in mortality in the patients taking Ac-

timmune compared to those taking placebo. And among patients treated at relatively early stages of the disease, there was a 70% reduction in mortality for those taking Actimmune compared to those taking placebo. As required by the securities laws, the company issued a press release reporting these results. The press release described the study as "demonstrat[ing] a … survival benefit." C.A.E.R. 1047.

The government conceded that the study was well designed and had been properly conducted, and that every piece of data in the press release was entirely accurate. But the government argued that it was a crime to describe these results as demonstrating anything at all. The government's theory was that there was a hard and fast law of science: Conclusions about causation could only be drawn from data that demonstrated statistical significance as measured by what is known as the "p-value test." In the government's world, statistical significance, measured by a p-value less than or equal to .05, was the gateway to drawing scientific conclusions. *See* C.A.E.R. 594-597. The government elicited testimony supporting this theory from a statistician. Summing up this theory in closing argument, the prosecution told the jury that because the study failed to meet the p-value test, "you can't draw any conclusions from this trial." *Id.* at 595.

More than six years after the jury convicted Dr. Harkonen, the American Statistical Association (ASA) issued a statement of fundamental principles declaring the government's statistical theory wrong. In particular, the ASA explained that the concept of statistical significance had been "misused and misinterpreted," that reliance on p-values "leads to considerable distortion of the scientific process," and that a "p-value, or statistical significance, does not measure the size of an

effect or importance of a result," and is "not equivalent to scientific, human, or economic significance." Wasserstein & Lazar, *The ASA's Statement on* p-*Values: Context, Process, and Purpose*, 70 Am. Statistician 129, 131-132 (2016) (ASA Principles)). In fact, p-values "do[] not provide a good measure of evidence regarding a model or hypothesis," and "[s]cientific conclusions … should not be based only on whether a *p*-value passes a specific threshold." *Id.*[1]

Because Dr. Harkonen was no longer in custody, he petitioned for a writ of error coram nobis to avoid the lingering adverse consequences of his conviction. The Ninth Circuit found Dr. Harkonen's evidence of actual innocence "compelling" but, because it found Dr. Harkonen had not shown an intervening change in law or an independent constitutional error in the conduct of the trial, it held that he had not "establish[ed] that his trial resulted in a manifest injustice warranting issuance of the writ." App. 2a. In doing so, the Ninth Circuit deepened a circuit split over whether a petitioner is entitled to coram nobis relief upon a showing of new evidence demonstrating his actual innocence, or whether a petitioner must also allege a constitutional or jurisdictional error in the proceedings leading to his conviction. This Court should grant certiorari to resolve that important question.

Although the question whether new evidence of actual innocence justifies coram nobis relief can arise in a variety of contexts, it is particularly important where, as here, the new evidence consists of scientific developments that discredit key evidence or theories used at

[1] The ASA Principles are available at https://amstat.tandfonline.com/doi/pdf/10.1080/00031305.2016.1154108?needAccess=true.

trial. The history of criminal law is replete with examples of convictions founded on bad science, whether it be Comparative Bullet Lead Analysis, *see Maryland* v. *Kulbicki*, 136 S. Ct. 2, 3-4 (2015) (per curiam), outdated understandings of burn patterns in arson science, *see Gavitt* v. *Born*, 835 F.3d 623, 630-636 (6th Cir. 2016), or, as here, misplaced reliance on the concept of statistical significance. Fundamental fairness requires that there be a mechanism to challenge such convictions, but a defendant cannot bring a motion for a new trial when, as is often the case, the scientific developments come to light more than three years after the defendant is convicted, *see* Fed. R. Crim. P. 33(b)(1), and constitutional challenges to these convictions are often unavailing, *see Kulbicki*, 136 S. Ct. at 4-5 (rejecting an ineffective-assistance-of-counsel claim because counsel could not have been expected to predict that Comparative Bullet Lead Analysis would be discredited).

In these cases, the only potential remedy is a free-standing claim of actual innocence based on new evidence. And where the science has taken years to develop, the defendant will frequently be out of custody before the evidence proving his innocence is discovered, and the only mechanism for seeking relief is a coram nobis petition. Under the Ninth Circuit's rule—and that of four other circuits—innocent defendants whose convictions are premised on discredited science have no plausible avenue for relief. This Court should grant certiorari to resolve the circuit split and affirm that—at least where new scientific evidence irrefutably establishes actual innocence—defendants may obtain relief through a petition for a writ of error coram nobis.

STATEMENT

A. Background

Dr. Harkonen is an accomplished medical doctor, researcher, and biotechnology executive. His work has led to the approval of FDA labeling for five new disease indications, including three for rare, orphan diseases. In 1998, Dr. Harkonen founded InterMune, a biotechnology company focused on developing new treatments for unmet medical needs. InterMune began trading as a public company in 2000, and Dr. Harkonen served as InterMune's CEO until 2003. *See United States* v. *Harkonen*, 2010 WL 2985257, at *1 (N.D. Cal. July 27, 2010).

One of the therapies under development at InterMune was Actimmune. *Harkonen*, 2010 WL 2985257, at *1. Actimmune is a bio-engineered form of interferon gamma that occurs naturally in the human body and that inhibits fibrosis that scars lung tissue. Actimmune had been approved for two other orphan diseases. Researchers found that in IPF, patients have abnormally low levels of interferon gamma in their bodies. This observation, along with Actimmune's ability to inhibit fibrosis, suggested it might be useful in treating IPF, which involves fibrotic scarring of lung tissue. *Id.* There were no approved treatments for IPF.

In 1999, the New England Journal of Medicine published the results of a randomized, controlled trial involving 18 patients with IPF (the "Phase II trial"). InterMune had no role in the trial. After twelve months, the patients receiving interferon gamma had meaningful improvement in lung function tests. *See* C.A.E.R. 529. The long-term survival status of the Phase II study patients was assessed over five years; 78% of the patients who received interferon gamma remained

alive, while only 16% in the control group survived. The p-value for this result was .009. *Id.* at 282, 1048.

Because Actimmune was already approved by the FDA for other uses, InterMune had the option of conducting no further research, and letting doctors choose to prescribe Actimmune based on the Phase II trial. Instead, after consultation with the FDA, InterMune decided to fund a gold-standard, double-blind, multicenter clinical study (the GIPF-001 study) to develop further information on the safety and efficacy of Actimmune as a treatment for IPF. *See* App. 7a. A Steering Committee of leading experts in pulmonary medicine and IPF supervised the trial, which enrolled 330 patients at 58 different study locations. C.A.S.E.R. 626, 652.

The results of the GIPF-001 study were reported to InterMune in August 2002. On safety, the drug was very well tolerated, confirming that physicians could prescribe Actimmune for IPF patients without harming them. C.A.E.R. 1048. On efficacy, the results were mixed. The primary efficacy endpoint—progression-free survival—showed approximately a 10% reduction in death or disease progression, but the effect was too small to be clinically meaningful to patients with IPF. *Id.* The result also did not achieve statistical significance on the "p-value" test. *Id.* at 1047.

While the data did not meet the study's primary endpoint, the results on the mortality endpoints were compelling. Across the entire study population, the mortality rate among those who took Actimmune was 40% lower than in the group taking the placebo, C.A.E.R. 1048, a result consistent with the overall mortality benefit observed in the long-term follow-up to the Phase II trial. The p-value for this result was .084. *Id.*

The mortality results were even more pronounced among patients with mild-to-moderate IPF (254 out of the 330 patients in the study, *id.*). In that group, the survival rate was 70% higher for patients taking Actimmune than for those taking placebo. *Id.* Only 6 of the 126 patients on Actimmune died during the study. *Id.* More than three times as many—21 of the 128 patients on the placebo—died. *Id.* The p-value for this result was .004. *Id.*

The size and consistency of the mortality results across two independent studies, and the persistence of the results across the entire population in the Phase III trial, and across various large subgroups in that trial, made a powerful case that there was a real mortality benefit.[2]

The graphs below depict what is known as a Kaplan-Meier analysis, and illustrate the dramatic survival advantage for patients taking Actimmune as compared to placebo in the Phase III trial.

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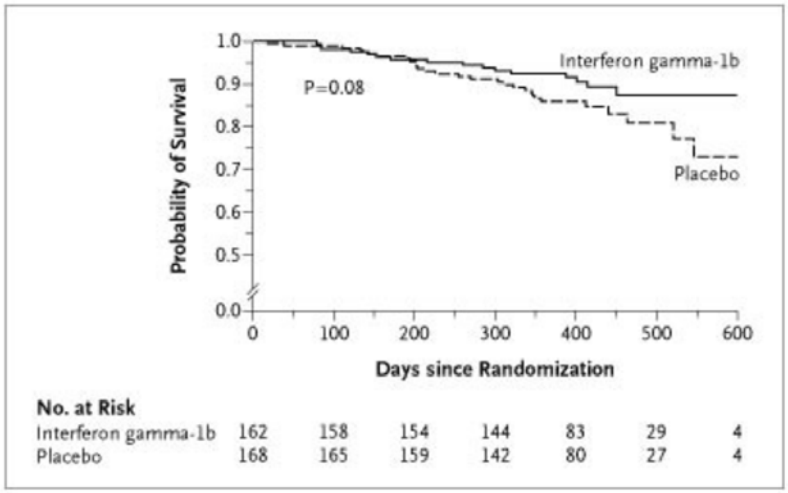
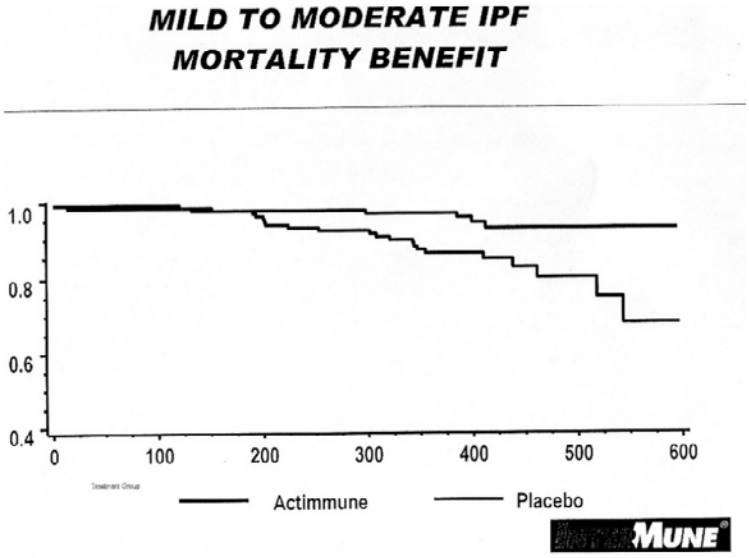
[2] Indeed, a later, independent meta-analysis of the data from the Phase II and Phase III trials, among other trials, concluded that interferon gamma "treatment is associated with decreased mortality." Bajwa et al., *Interferon-γ1b Therapy in Idiopathic Pulmonary Fibrosis*, 128 Chest 203, 206 (2005).





12/4/2009 Topel Decl. Ex. S at 6 (D. Ct. Dkt. 249-6); C.A.E.R. 2366, *United States* v. *Harkonen*, Nos. 11-10209 & 11-10242 (9th Cir. Oct. 31, 2011). The analyses show the large separation between the survival rates for the drug and placebo group, and that the separation increased over time.

Other data points in the study also supported the inference that Actimmune reduced mortality for IPF patients. There was a trend in favor of Actimmune in terms of both improved breathing and reduced need for supplemental oxygen. C.A.E.R. 1048. The results were reviewed at an off-site meeting on August 27 with the company's employees and with the study's Steering Committee and principal investigators.

Once the GIPF-001 study's results were disclosed to the corporate outsiders for their review and analysis, InterMune was obligated by federal securities law prohibiting selective disclosure promptly to disclose those results to investors and the public. C.A.E.R. 753, 808-809, 811-815; *see* 17 C.F.R. § 243.100. Accordingly, InterMune issued a press release, held a conference call, and posted the top line results of the GIPF-001 study on its website on August 28, 2002. C.A.E.R. 1047-1050; 12/4/2009 Topel Decl. Ex. SS (D. Ct. Dkt. 249-13).[3]

The press release's headline stated: "InterMune Announces Phase III Data Demonstrating Survival Benefit of Actimmune in IPF." C.A.E.R. 1047 (capitalization altered). The subtitle read: "Reduces Mortality by 70% in Patients with Mild to Moderate Disease." *Id.*

The release further stated that the "preliminary" data "demonstrate a significant survival benefit in pa-

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[3] At trial, the government focused heavily on the mechanics of the preparation of the press release, urging the jury to find a culpable mental state from Dr. Harkonen's efforts to limit the number of people involved in drafting the release. That argument was misdirected, because limiting the number of people involved in coordinating the release of material, non-public information was routine and appropriate, particularly where, as here, the release included revisions to its future earnings projections.

tients with mild to moderate disease randomly assigned to Actimmune versus control treatment (p=0.004)." C.A.E.R. 1047. It stated in the first paragraph that there was a 10% reduction in progression-free survival and that this result was not statistically significant. *Id.* at 1047, 1048. It explained that the preliminary results were part of a continuing study to track "longer term outcomes." *Id.* at 1047-1050. And the press release provided the underlying data on the survival benefit, including the number of patients who lived and died and the associated p-values for the study group as a whole and for those patients who comprised the mild-to-moderate-IPF subgroup. *Id.* at 1048; *see also id.* at 723:20-21.

The press release was only InterMune's initial disclosure related to the study. As promised in the release, that same day, InterMune conducted a conference call with investors at which additional details of the study results were discussed. *See* 12/4/2009 Topel Decl. Ex. SS (D. Ct. Dkt. 249-13). And over the next several weeks, leading physicians involved in the study provided comprehensive analyses of the study results, including the same survival analyses presented in the press release, at various medical conferences. *See* 12/4/2009 Topel Decl. Exs. C, Z (D. Ct. Dkts. 249-1, 249-6). Thereafter, InterMune met with the FDA to review the study results and discuss requirements for including an IPF indication in Actimmune's labeling.

B. Dr. Harkonen's Trial And Appeal

The government launched an investigation of InterMune largely focused on allegations of "misbranding," that is, that InterMune encouraged doctors to prescribe Actimmune for IPF without obtaining FDA approval to market it for that use. In 2006, InterMune

entered into a deferred prosecution agreement and paid a settlement. C.A.S.E.R. 4031.

In 2008, Dr. Harkonen was indicted, both for misbranding, in violation of 2 U.S.C. §§ 331(k), 333(a)(2), and 352(a), and for wire fraud, in violation of 18 U.S.C. § 1343. C.A.E.R. 1036-1045. The premise of the wire fraud charge was that the press release "falsely portrayed the results of the GIPF-001 Phase III trial as establishing that Actimmune helped IPF patients live longer." *Id.* at 1041. The only statements specifically alleged to be false were the press release's headline and subheading. *Id.* at 1041-1042. These statements were allegedly made "to induce doctors to prescribe, and patients to take, Actimmune to treat IPF." *Id.* at 1041.

At trial, the government acknowledged that the press release accurately reported the data from the GIPF-001 study. But the government took issue with the conclusions about those data as stated in the headline and subheading of the release. The government's theory was that "no reasonable scientist could have, in good faith, reported the trial to be anything but an abject failure because its results did not meet certain statistical principles [the government] argued were immutable." App. 6a-7a.

Specifically, the government argued that because the study failed to achieve statistical significance, no conclusions could be drawn from the trial. C.A.E.R. 212-214; *see also id.* at 3, 594-596. As the prosecution argued in summation: "The only meaningful p-value for this trial is the p-value for the primary endpoint. And that p-value was 0.5; nowhere near statistical significance. What that p-value means … [is] that you can't draw any conclusions from this trial." *Id.* at 595. Thus, the government's case expressly relied on a particular

(and subsequently-discredited) view of statistical significance: that because the study results did not meet the p-value test for statistical significance, the data was unreliable and no inferences could be drawn from the study.[4]

On September 29, 2009, the jury found Dr. Harkonen guilty of wire fraud and not guilty of misbranding. C.A.E.R. 550. Dr. Harkonen moved for a judgment of acquittal for insufficient evidence and on First Amendment grounds and for a new trial. *Id.* The district court denied the motion on July 27, 2010. *Id.* at 550-582. In doing so, the court relied on the testimony of the government's witnesses that "a p-value of 0.05 is somewhat of a magic number," *id.* at 557, and that if the primary endpoint fails to achieve a p-value of less than .05, no conclusions can be drawn from the trial, *id.* at 558-559.

On February 14, 2011, prior to sentencing, Dr. Harkonen filed a second new trial motion. Dr. Harkonen argued that an amicus brief filed by the United States in *Matrixx Initiatives, Inc.* v. *Siracusano*, 563 U.S. 27 (2011), constituted newly-discovered exculpatory evidence because the government took a position in that brief that "directly conflict[ed] with the testimony it elicited at trial and argued to the jury." 2/14/2011 Mot. for New Trial 12 (D. Ct. Dkt. 322). Specifically, the United States took the position in *Matrixx* that "a determination that certain data are not statistically

[4] Just as the prosecution was taking this position in Dr. Harkonen's trial, the NIH was issuing a press release touting the success of an HIV vaccine trial despite argument that "per protocol" results were not statistically significant. *See* 12/4/2009 Motion to Dismiss 19 (D. Ct. Dkt. 247).

significant … does *not* refute an inference of causation" and that "causation can appropriately be inferred through consideration of multiple factors *independent* of statistical significance." *Id.* at 1 (internal quotation marks omitted; alteration in the original).

In opposing the new trial motion, the government sought to recharacterize its brief in *Matrixx*. The *Matrixx* brief, according to the government, was about whether investors might care about safety data drawn from a statistically insignificant number of adverse events. But the *Matrixx* brief, the government argued, did not resolve the role of statistical significance in drawing conclusions about efficacy from study data. In the government's view, it remained improper to "assert that statistically insignificant data proves a drug works." 3/7/2011 Opp. to Mot. for New Trial 7 (D. Ct. Dkt. 343).

In the midst of the briefing on the new trial motion, this Court issued its decision in *Matrixx*. Relying in large part on the government's amicus brief, this Court rejected the argument that "statistical significance is the only reliable indication of causation," and stated that "[a] lack of statistically significant data does not mean that medical experts have no reliable basis for inferring a causal link between a drug" and observed clinical outcomes. *Matrixx*, 563 U.S. at 40. Moreover, the Court acknowledged that "medical experts rely on other evidence to establish an inference of causation." *Id.* For example, researchers and clinicians consider the "strength of the association" and "temporal relationship" between a drug and the observed outcome; "consistency across studies; biological plausibility; consideration of alternative explanations; specificity …; the dose-response relationship; and the clinical and pathological characteristics of the event." *Id.* at 40 n.7.

Notwithstanding *Matrixx*, the district court denied Harkonen's motion for a new trial. C.A.E.R. 228. On April 13, 2011, the court imposed a sentence of three years' probation and six months' home detention. *Id.* at 232-237.

The Ninth Circuit affirmed Dr. Harkonen's conviction and sentence. *United States* v. *Harkonen*, 510 F. App'x 633, 635 (9th Cir. 2013). Dr. Harkonen petitioned for certiorari, arguing that a conclusion about the meaning of scientific data cannot be a "false or fraudulent" statement within the meaning of the wire fraud statute and that applying that statute to scientific conclusions would violate the First Amendment's proscription against viewpoint discrimination. Pet., *Harkonen* v. *United States*, No. 13-180 (U.S. Aug. 5, 2013). This Court denied certiorari on December 16, 2013. 571 U.S. 1110 (2013).

C. Petition For A Writ Of Error Coram Nobis

On July 30, 2014, Dr. Harkonen filed a petition for a writ of error coram nobis in the district court challenging the statistical basis for the government's theory at trial. 7/30/2014 Pet. for Writ of Error Coram Nobis (D. Ct. Dkt. 399).[5] Dr. Harkonen explained that the government statistical witness's testimony regarding the

[5] The writ of error coram nobis provides a way to collaterally attack a conviction for a person, like Dr. Harkonen, who is no longer in custody and therefore cannot seek habeas relief or file a § 2255 motion. *Chaidez* v. *United States*, 568 U.S. 342, 345 n.1 (2013); *see* 28 U.S.C. § 2241(c) ("The writ of habeas corpus shall not extend to a prisoner unless … [h]e is in custody …."); *id.* § 2255(a) ("A prisoner *in custody* under sentence of a court … may move the court which imposed the sentence to vacate, set aside or correct the sentence." (emphasis added)).

proper interpretation of data and the import of data showing statistically-insignificant results was inconsistent with generally-accepted principles of biostatistics. 7/30/2014 Memo ISO Pet. for Writ of Error Coram Nobis 72-74 (D. Ct. Dkt. 399-1). The district court denied the petition as untimely on August 21, 2015. App. 5a, 17a-22a.

Dr. Harkonen appealed the district court's denial of his petition. On appeal, he argued that a recent scientific development had disproven the theory upon which he was convicted. Dr. Harkonen explained that the American Statistical Association had, in 2016—more than six years after the jury found him guilty—promulgated a statement of six fundamental principles that govern the field of statistics. Pet. C.A. Br. 43-44 (citing the ASA Principles). Dr. Harkonen argued that the ASA Principles "declare[] to be false" "precisely the statistical propositions" on which the "government convicted Dr. Harkonen." *Id.* at 44. Accordingly, "his conviction must now be declared void." *Id.*

The ASA issued these principles because the concept of statistical significance and the use of p-values had been "commonly misused and misinterpreted," which had led to "considerable distortion of the scientific process." ASA Principles 131. Through the Principles, the ASA sought to "improve the conduct or interpretation of quantitative science" by "clarifying … principles underlying the proper use and interpretation of the *p*-value" based on "widespread consensus in the statistical community." *Id.*

The conclusions from the ASA Principles are the opposite of the government's theory of guilt. The government presented statistical significance as the gateway through which clinical trial data must pass, with p-

values as "magic number[s]" that determine the reliability of study results. C.A.E.R. 557. The government flatly told the jury that the p-value on the primary endpoint, by itself, showed the study had "failed" and precluded drawing any conclusions from it. *Id.* at 594-595.

The ASA Principles establish that the scientific consensus is now squarely to the contrary. The ASA Principles explain that the consensus of statisticians is that statistical significance is not the gateway to sound inferences from study data, and p-values are not magic at all. Indeed, "[*p*]-values do not measure the probability that the studied hypothesis is true, or the probability that the data were produced by random chance alone." ASA Principles 131.[6] Thus, "[a] conclusion does not immediately become 'true'" if data generates a particular p-value (such as less than .05) or (more importantly here) "'false'" if it does not. *Id.*[7] Nor does a p-value "measure the size of an effect or the importance of a result." *Id.* at 132.

All that is consistent with this Court's statement in *Matrixx* that a lack of statistical significance is not a bar to causation, and that scientists appropriately consider other factors. But the ASA Principles go much further. They explain that p-values are not an im-

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[6] The district court, in upholding the verdict, had said just the opposite: "The lower a p-value is, the greater probability that the result perceived in the data is not due to chance." C.A.E.R. 557.

[7] Again, the district court in upholding the verdict had said precisely the opposite: Simply because the "data for the secondary endpoint of survival time yielded a p-value [higher than .05] … the jury could have concluded beyond a reasonable doubt that [the press release] … was false." C.A.E.R. 563.

portant tool in assessing causation. To the contrary, "[b]y itself, a *p*-value does not provide a good measure of evidence regarding a model or hypothesis." ASA Principles 132. A low p-value "offers only weak evidence against the null hypothesis." *Id.* And a "relatively large *p*-value does not imply evidence in favor of the null hypothesis." *Id.*[8] Accordingly, as the ASA Principles state, "[s]cientific conclusions and business or policy decisions should not be based only on whether a *p*-value passes a specific threshold." *Id.* at 131. Rather, researchers "should bring many contextual factors into play to derive scientific inferences, including the design of a study, the quality of the measurements, the external evidence for the phenomenon under study, and the validity of assumptions that underlie the data analysis." *Id.*

Dr. Harkonen argued (Pet. C.A. Br. 43-48) that the current understanding of statistical significance and p-values—as reflected in the ASA Principles—directly undermines the government's theory at trial that no reasonable scientist could "conclude that Actimmune has a survival benefit" simply because the GIPF-001 trial did not yield statistically significant results. C.A.E.R. 595. With p-values in their proper place—not as magic numbers, or a gateway that must be crossed before drawing conclusions, but rather as evidence too "weak" to form the basis for scientific conclusion—the "logical conclusion from [the survival] data was that it showed or 'demonstrated' a mortality benefit," as stated in the press release. Pet. C.A. Br. 44. Accordingly,

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[8] The "null hypothesis" in the context of a drug trial is the hypothesis that there is no evidence of an association between the drug and the effect.

the conclusions stated in the press release could not be false or fraudulent.

In response, the government acknowledged that "experts can use statistically insignificant data coupled with other information to infer a link between a drug and a particular effect in patients." Resp. C.A. Br. 66. But it maintained that this pivotal concession "has nothing to do with Harkonen's conviction," which it instead attributed to the supposed fact that Dr. Harkonen "did not rely on other evidence in asserting that the clinical trial results supported the inference that Actimmune was responsible for a survival benefit." *Id.* That argument, of course, was never made to the jury, which was instead told that the statistical results, by themselves, precluded drawing conclusions from the study. It is also contrary to the plain language of the press release, which refers expressly to other evidence, such as the Phase II study results, and the supportive trends on other endpoints. And it does not reckon with the ASA Principles, which make clear something the jury was never told: The p-value results do *not* count as important evidence *against* the efficacy conclusion.

The Ninth Circuit rejected the government's effort to salvage the factual basis for the conviction. Instead, the court of appeals found Dr. Harkonen's "proffered evidence" of innocence "compelling, especially in light of *Matrixx*." App. 2a. Nevertheless, it affirmed the judgment below. For the Ninth Circuit, innocence was not enough. To be entitled to relief, Dr. Harkonen needed to point to a "change in controlling law." *Id.* Because he had not done so, the court held that he had failed to "establish that his trial resulted in a manifest

injustice warranting issuance of [a] writ" of error coram nobis. *Id.*[9]

Dr. Harkonen filed a petition for rehearing and rehearing en banc arguing that the Ninth Circuit had erred in denying his coram nobis petition despite finding his claim of actual innocence "compelling." Pet. C.A. Reh'g Pet. 10-16. Dr. Steven Goodman, Associate Dean of Clinical and Translational Research and Professor of Medicine and of Health Research and Policy at Stanford University, filed an amicus brief in support of Dr. Harkonen. Dr. Goodman confirmed that the ASA's statement of principles "utterly discredited" the "government's 'immutable' theory of statistics upon which it obtained Dr. Harkonen's conviction" and demonstrated Dr. Harkonen's innocence. Goodman C.A. Br. 9. Dr. Goodman added that "leaving this conviction in place would represent an implicit endorsement of scientific falsehoods," which "does not serve the courts, science or society well." *Id.* at 7. The Ninth Circuit called for a response, but denied Dr. Harkonen's petition for rehearing on June 1, 2018. App. 29a-30a.

REASONS FOR GRANTING THE PETITION

I. THE COURT SHOULD GRANT REVIEW TO CONSIDER WHETHER A CLAIM OF NEW EVIDENCE DEMONSTRATING ACTUAL INNOCENCE CAN EVER JUSTIFY CORAM NOBIS RELIEF

A petition for a writ of error coram nobis provides a way to collaterally attack a criminal conviction when the petitioner is no longer "in custody," and therefore

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[9] The court did not reach the question whether Dr. Harkonen's coram nobis petition was timely. App. 4a n.1.

cannot seek relief under 28 U.S.C. §§ 2241 or 2255. *Chaidez* v. *United States*, 568 U.S. 342, 345 n.1 (2013) *see also United States* v. *Morgan*, 346 U.S. 502, 506-511 (1954). Like habeas corpus, the writ of error coram nobis was originally confined to cases where the tribunal lacked jurisdiction or where other errors rendered the proceeding invalid. At common law, coram nobis was available to correct "errors in matters of fact which … were material to the validity and regularity of the legal proceeding itself; as where the defendant, being under age, appeared by attorney, or the plaintiff or defendant was a married woman at the time of commencing the suit, or died before verdict or interlocutory judgment." *United States* v. *Mayer*, 235 U.S. 55, 68 (1914). But the scope of coram nobis—like that of habeas corpus—has been expanded to provide a remedy for a variety of constitutional errors or otherwise-unjust verdicts. As the Court said in *Morgan*, although the writ of error coram nobis is generally described by reference to a narrow set of instances warranting relief, *see, e.g.*, *Mayer*, 235 U.S. at 68, "its use has been by no means so limited," *Morgan*, 346 U.S. at 507-508; *see also United States* v. *Denedo*, 556 U.S. 904, 910-911 (2009).

Although the Court has spoken of coram nobis in general terms, it has not "addressed the precise standards that lower courts should use in deciding whether to issue" the writ. *Murray* v. *United States*, 704 F.3d 23, 29 (1st Cir. 2013). One question, in particular, that arises on coram nobis review is whether a court may grant the writ based on new evidence of actual innocence. It often takes years for new evidence to materialize, by which point defendants have frequently completed any term of imprisonment and coram nobis is the only avenue for seeking relief. The courts of appeals

have taken differing positions on whether an actual-innocence claim warrants coram nobis relief. The Court should grant certiorari to resolve that split and confirm that where a petitioner presents compelling evidence of actual innocence, coram nobis relief is available.

A. The Circuits Are Split On Whether A Pure Actual Innocence Claim Based On New Evidence Meets The Standard For Coram Nobis

The Second, Third, Seventh, Ninth, and Eleventh Circuits have held that a freestanding claim of actual innocence does not warrant coram nobis relief. In those circuits, a petitioner must allege a constitutional or jurisdictional error. In contrast, courts in the Sixth, Eighth, and Tenth Circuits will grant coram nobis relief if the petitioner brings newly-discovered evidence demonstrating his actual innocence.

1. Five circuits, including the Ninth Circuit in this case, have held that a "claim of newly discovered evidence relevant … to the guilt or innocence of the petitioner is not cognizable in a coram nobis proceeding." *Moody* v. *United States*, 874 F.2d 1575, 1577 (11th Cir. 1989). In those circuits, even a petitioner who presents new evidence conclusively demonstrating his innocence cannot obtain relief unless that evidence reveals an independent "constitutional or jurisdictional error." *Foont* v. *United States*, 93 F.3d 76, 80 (2d Cir. 1996).

In *Moody*, for example, Walter Moody had been convicted of possessing an unregistered destructive device. 874 F.2d at 1576. Moody petitioned for coram nobis relief on the ground that new evidence proved that he did not commit the crime. *Id.* The Eleventh Circuit rejected the claim without considering its merits, stating that "newly discovered evidence affords no

entrée to the writ." *Id.* at 1577 (internal quotation marks and brackets omitted); *see also United States* v. *Mills*, 221 F.3d 1201, 1205 (11th Cir. 2000) ("allegations of newly discovered evidence are not cognizable in a petition for coram nobis").

The Ninth Circuit has taken a particularly narrow view of coram nobis, stating that, to warrant relief, a coram nobis petition must present a "constitutional controversy." *Byrnes* v. *United States*, 408 F.2d 599, 602 (9th Cir. 1969); *see also Telink, Inc.* v. *United States*, 24 F.3d 42, 45 (9th Cir. 1994) ("The writ of error coram nobis affords a remedy to attack an unconstitutional or unlawful conviction in cases when the petitioner already has fully served a sentence."). A free-standing claim of actual innocence—one in which the petitioner has discovered new evidence that proves that he did not commit the crime of conviction, but where he cannot establish that an independent constitutional error infected the proceedings that led to conviction—does not warrant coram nobis relief.[10]

The Second, Third, and Seventh Circuits have similarly held that a petitioner cannot obtain coram nobis relief by showing only that he is innocent of the crime of conviction; the petitioner must *also* demonstrate an independent constitutional or jurisdictional error. *See*

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[10] The Ninth Circuit applied this heightened standard here. The court recognized that Dr. Harkonen's "proffered evidence"—which demonstrated that the conclusions stated in the press release were well within the realm of reasonable scientific debate—were "compelling." App. 2a. The court of appeals denied the writ nonetheless, finding that this demonstration of actual innocence did "not establish that [Dr. Harkonen's] trial resulted in a manifest injustice warranting issuance of the writ," because he had not "point[ed] to [any] change in controlling law." *Id.*

Foont, 93 F.3d at 80 ("Claims of new evidence, … without constitutional or jurisdictional error in the underlying proceeding, cannot support a coram nobis claim."); *United States* v. *Stoneman*, 870 F.2d 102, 106 (3d Cir. 1989) ("The error must go to the jurisdiction of the trial court, thus rendering the trial itself invalid."); *United States* v. *Scherer*, 673 F.2d 176, 178 (7th Cir. 1982) ("[T]he burden is on the petitioner to demonstrate that 'the asserted error is jurisdictional or constitutional, and involves an error of law that results in a complete miscarriage of justice.'" (internal brackets omitted)); *United States* v. *Hedman*, 655 F.2d 813, 815 (7th Cir. 1981) (coram nobis "[r]elief … is available only if the asserted error is jurisdictional or constitutional").

2. Three circuits, in contrast, will recognize a claim of new evidence demonstrating actual innocence in a coram nobis petition. The Eighth Circuit, for example, has rejected the argument "that *coram nobis* relief is not available for claims based on newly discovered evidence." *Kandiel* v. *United States*, 964 F.2d 794, 797 n.1 (8th Cir. 1992) (per curiam). The *Kandiel* court ultimately did not grant the writ, finding that the new evidence did not "constitute[] positive proof" of the petitioner's innocence. *Id.* at 797. But the Eighth Circuit confirmed that coram nobis relief is available for compelling new evidence that undermines the factual basis for a conviction. *Id.* at 797 n.1; *see also Azzone* v. *United States*, 341 F.2d 417, 419 (8th Cir. 1965) (per curiam) (considering petitioner's claim "that he has newly discovered evidence which proves that he did not violate 18 U.S.C.A. § 1073").

Similarly, the Tenth Circuit has not limited coram nobis relief to cases in which the petitioner can demonstrate a constitutional or jurisdictional error, stating more generally that "a writ of error *coram nobis* is

available … to correct errors resulting in a complete miscarriage of justice, or under circumstances compelling such action to achieve justice." *United States* v. *Bustillos*, 31 F.3d 931, 934 (10th Cir. 1994). And the Tenth Circuit has held that "[a] colorable showing of factual innocence demonstrates a fundamental miscarriage of justice." *United States* v. *Miles*, 553 F. App'x 846, 848 (10th Cir. 2014) (internal quotation marks omitted). Indeed, in *Bustillos*, the court rejected the petitioner's claim that an insufficient factual basis was presented at the plea hearing to support his guilty plea because, the court stated, he had "not assert[ed] his innocence of the charge to which he pleaded guilty." 31 F.3d at 934.

The Sixth Circuit's standard for coram nobis relief also permits the writ to issue upon a showing of compelling new evidence. The court has stated that to obtain relief, a coram nobis petitioner must show "(1) an error of fact; (2) unknown at the time of trial; (3) of a fundamentally unjust character *which probably would have altered the outcome of the challenged proceeding* if it had been known." *United States* v. *Johnson*, 237 F.3d 751, 755 (6th Cir. 2001) (emphasis added); *see also Barrow* v. *United States*, 455 F. App'x 631, 634-637 (6th Cir. 2012) (affirming denial of writ because petitioner did not present new evidence that would have "altered the outcome of the entire proceeding").

B. Dr. Harkonen's Compelling New Evidence Of Actual Innocence Would Have Warranted Relief In The Sixth, Eighth, And Tenth Circuits

The Ninth Circuit found Dr. Harkonen's evidence of actual innocence "compelling." App. 2a. That finding was plainly correct. The government told the jury that the press release was false because the trial results

were not statistically significant. The ASA Principles are squarely to the contrary: P-values are not a measure of a proposition's truth or falsity. A p-value is "weak evidence" insufficient to determine the clinical meaning of study data. ASA Principles 132. Indeed, no "[s]cientific conclusions" at all—much less a mandate to ignore all evidence from a study—should be "based only on whether a *p*-value passes a specific threshold." *Id.* at 131.[11]

Absent the government's statistical theory that the p-value precluded drawing any conclusions from the study data, the statements in the press release were uncontroversial. In two consecutive studies—the long-term follow-up to the Phase II trial, and the Phase III trial InterMune conducted—patients taking Actimmune were much more likely to survive than those taking placebo. The trend was large, and continued for years in both trials.

Such "consistency across more than one study" is (unlike p-values), highly relevant in assessing causation, since it "greatly reduc[es] the possibility that a biased, chance, site-specific, or fraudulent result will lead to an erroneous conclusion that a drug is effective." FDA, *Guidance for Industry: Providing Clinical Evidence for Human Drug and Biological Products* 5 (1998), *at* https://tinyurl.com/ya2aentj; *see also Matrixx*, 563 U.S. at 41 ("'consistency of findings across available data sources'" is relevant in assessing causation). Moreover, the study was well designed, there

[11] Many statisticians now conclude that "[t]here are no good reasons nor good ways to use p-values," and that reporting them in scholarly journals should be proscribed. Briggs, *The Substitute for p-Values*, 112 J. Am. Stat. Ass'n 897, 897 (2017).

appeared to be a dose-response relationship,[12] the survival benefit appeared to increase over time, and there was a plausible biologic basis to believe Actimmune—which had known anti-fibrotic properties—would work for IPF patients. *See Matrixx*, 563 U.S. at 41 (discussing role of "'dose-response,'" "'temporal relationship,'" and "'biologic plausibility'" in assessing causation); ASA Principles 132 (discussing role of "good study design" in assessing causation). In short, the inferences stated in the press release are amply supported by the kinds of evidence that scientists should rely on. The government told the jury something very different. It insisted that lack of statistical significance, measured by p-values, was enough to make the results unreliable and the press release fraudulent. But the ASA Principles now establish p-values have no magic power to outweigh compelling evidence of causation; they are instead evidence too "weak" to form the basis for "scientific conclusions." ASA Principles 131-132.

Dr. Harkonen's claim of new evidence is thus quite unlike, and much stronger than, the usual case in which new evidence casts doubt on the facts proven at trial. The new evidence in this case demonstrates that *the prosecution's own version* of the facts does not establish the crime alleged. This is not a case where Dr. Harkonen is relying on after-the-fact affidavits, or witness recantations, or belatedly challenging who said what to whom. Rather, the new evidence establishes that the metric by which the government asked the jury to judge the truth or falsity of Dr. Harkonen's undisputed statements in the press release was itself flatly wrong. The jury was told that because the study's p-

[12] *See* 3/23/2009 Topel Decl. Ex. 1 at 1 (D. Ct. Dkt. 89-1).

values failed to hit a "magic" number, no conclusions could be drawn from the study; on that premise, the jury had little choice but to find the press release inaccurate. Had the jury instead been told that p-values "do[] not provide a good measure of evidence regarding a model or hypothesis," ASA Principles 132, and that scientists instead focus on issues such as consistency of results across trials, the jury would have had no option other than to acquit.

Because the new evidence in this case undermines the government's entire theory of guilt, and not just one piece of evidence, Dr. Harkonen has established his actual innocence under any possible standard. *Cf. Herrera* v. *Collins*, 506 U.S. 390, 417 (1993) (assuming that "a truly persuasive demonstration of 'actual innocence' made after trial would render the execution of a defendant unconstitutional"); *id.* at 429 (White, J., concurring) ("To be entitled to relief, … petitioner would at the very least be required to show that based on proffered newly discovered evidence and the entire record before the jury that convicted him, 'no rational trier of fact could find proof of guilt beyond a reasonable doubt.'" (alterations omitted)); *id.* at 444 (Blackmun, J., dissenting) (a petitioner would be entitled to habeas relief if he could "show that he is probably actually innocent, in light of all the evidence"). The new evidence conclusively establishes that the government was relying on faulty scientific theories in arguing that rules of statistical significance made it impossible to draw any conclusions from the GIPF-001 study. No rational jury could convict Dr. Harkonen in light of the ASA's rejection of the government's false statistical theory.

As the Ninth Circuit recognized, there is compelling evidence of innocence. In the Sixth, Eighth, and Tenth Circuits, that would be enough to warrant coram

nobis relief. By the fortuity of having been tried in the Ninth Circuit, however, Dr. Harkonen remains convicted of a crime that the evidence now indicates he did not commit. That ought to be an intolerable result.

C. The Ninth Circuit Erred By Denying Coram Nobis Relief Despite Finding Dr. Harkonen's New Evidence "Compelling"

As explained above (at 21), coram nobis has been used to remedy a wide range of errors in criminal proceedings and generally "under circumstances compelling such action to achieve justice." *Morgan*, 346 U.S. at 511. Thus, the Court has "found that a writ of *coram nobis* can issue to redress a fundamental error" as well as "mere technical errors." *Denedo*, 556 U.S. at 911. In *Morgan*, for example, the Court held that coram nobis was available to review a claim of deprivation of counsel in violation of the Sixth Amendment. 346 U.S. at 512-513. Coram nobis has also been used to examine claims of insanity, *id.* at 510, that the government coerced witnesses to commit perjury, *id.*, and ineffective assistance of counsel, *Denedo*, 556 U.S. at 907.

There is no error more fundamental than the conviction of an innocent person. The Court should take this opportunity to hold that coram nobis relief is available to a petitioner who has made a compelling showing of actual innocence, at least where (as here) that showing is based on a new scientific consensus. In *Kuhlmann* v. *Wilson*, a plurality of the Court recognized that "a prisoner retains a powerful and legitimate interest in obtaining his release from custody if he is innocent of the charge for which he was incarcerated." 477 U.S. 436, 452 (1986). Thus, a defendant who shows that "a constitutional violation has probably resulted in [his] conviction" though he is "actually innocent" can

show a "fundamental miscarriage of justice" that will excuse any procedural default of a claim on habeas review. *Schlup* v. *Delo*, 513 U.S. 298, 321 (1995) (internal quotation marks omitted). The fundamental miscarriage of justice is just as clear here, and warrants extending collateral relief to a defendant who can demonstrate his innocence without regard to whether there was also independent constitutional error in the proceedings leading to his conviction.[13]

In *Herrera* v. *Collins*, the Court assumed without deciding that, at least in a capital case, "a truly persuasive demonstration of 'actual innocence' made after trial would render" punishment "unconstitutional, and warrant federal habeas relief." 506 U.S. at 417. Although the Court only assumed this rule, a majority of the justices agreed that a capital prisoner's demonstration of actual innocence would be grounds for relief from the conviction. Justice O'Connor, joined by Justice Kennedy, wrote in a concurrence that "the execution of a legally and factually innocent person would be a constitutionally intolerable event." *Id.* at 419. Justice Blackmun, joined by Justices Stevens and Souter, meanwhile, wrote in dissent that "if a prisoner can

[13] In recognizing that a showing of actual innocence can excuse a procedural default, the Court adopted a standard proposed by Judge Friendly. *Kuhlmann*, 477 U.S. at 454 (plurality opinion) (citing Friendly, *Is Innocence Irrelevant? Collateral Attack on Criminal Judgments*, 38 U. Chi. L. Rev. 142 (1970)); *see also Schlup*, 513 U.S. at 328 (adopting Judge Friendly's description of the actual-innocence inquiry, that the habeas court must determine the petitioner's innocence "'in light of all the evidence'"). Judge Friendly recognized that substantive claims of actual innocence should be considered on collateral review, even *without* an independent constitutional error. 38 U. Chi. L. Rev. at 159 n.87, 160.

show that he is probably actually innocent, in light of all the evidence, then he has made 'a truly persuasive demonstration [of innocence],' … and his execution would violate the Constitution." *Id.* at 444.

While the consequences of error are obviously uniquely high in the capital context, a petitioner who has completed his term of incarceration maintains a strong interest in avoiding the lingering consequences of a conviction for an offense of which he is actually innocent. Subsequent convictions may carry heavier penalties, *Morgan*, 346 U.S. at 512-513; a non-citizen may face deportation, *Denedo*, 556 U.S. at 907-908; and the individual may be deprived of certain civil rights, such as the ability to serve on a jury, vote, or hold office, *Fiswick* v. *United States*, 329 U.S. 211, 222 & n.10 (1946). A criminal record may also limit or prohibit individuals from accessing employment, occupational licensing, housing, education, adoption services, and other opportunities.[14] There is no legitimate reason to impose such burdens on a person who has demonstrated factual innocence. Indeed, doing so only undermines public confidence in the judicial system.

Where the new evidence demonstrating the defendant's innocence consists of changed science, that new evidence often will not be available for many years following the verdict because it takes time for science to change and new theories to find acceptance in the scientific community. By that time, other remedies—such as motions for a new trial—may no longer be available. Yet that kind of new evidence can be among

[14] Dr. Harkonen, for example, is subject to a lifetime bar from working for any company seeking FDA approval for a product.

the most compelling because it demonstrates that the evidence the jury relied upon does not prove what the government argued or expert witnesses testified that it proved. Moreover, where, as here, scientific developments discredit the entire premise of the government's case, justice requires a mechanism for the defendant to challenge his conviction.

The Court has recognized that the conviction of an innocent person is a "fundamental miscarriage of justice." *Schlup*, 513 U.S. at 321. There was just such a miscarriage here. The government told the jury that any conclusion drawn from the study was false because the study had a p-value greater than .05. But we now know that it was the government's statistical premise—not the press release's conclusions—that was false. The writ of coram nobis is an appropriate mechanism to obtain relief from such errors. *See, e.g.*, *United States* v. *Ridings*, 569 F. App'x 73, 75 (3d Cir. 2014) (per curiam) (denying coram nobis because petitioner had not "made the necessary showing of a 'complete miscarriage of justice'"); *Jimenez* v. *Trominski*, 91 F.3d 767, 768 (5th Cir. 1996) (coram nobis "will issue only to correct errors resulting in a complete miscarriage of justice"); *Bustillos*, 31 F.3d at 934 ("a writ of error *coram nobis* is available only to correct errors resulting in a complete miscarriage of justice, or under circumstances compelling such action to achieve justice"). The Court should take this opportunity to confirm that coram nobis can be used to grant relief from a conviction for a defendant who is able to make a compelling showing of innocence based on new evidence.

II. THIS CASE PRESENTS A GOOD VEHICLE TO ADDRESS THE STANDARD FOR CORAM NOBIS RELIEF

This case presents an ideal vehicle to address the question presented because the Court need not resolve any factual issues to reach that question. In particular, the Ninth Circuit has already found Dr. Harkonen's new evidence of actual innocence "compelling." App. 2a. It denied relief because Dr. Harkonen had not pointed to any "change in controlling law." *Id.* The question whether new evidence of actual innocence justifies coram nobis relief is thus cleanly presented here, and requires no fact finding from this Court.

Many coram nobis cases raising claims of actual innocence, by contrast, will raise subsidiary factual questions. Which pieces of evidence or what witnesses' testimony are called into doubt by the new evidence? Was the affected evidence harmless? Would the unaffected evidence have been sufficient to convict? But the Court need not address any of those questions in the present case because the new scientific evidence undermines the government's entire theory of guilt. Nor need the Court worry that it will not be able to reach the question presented because Dr. Harkonen could not demonstrate his innocence under the appropriate standard in any event. Because the scientific consensus undermines the theory of conviction, Dr. Harkonen can demonstrate his actual innocence, however stringent the standard.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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