06-2071-cv In re Ephedra Products Litigation

1	UNITED STATES COURT OF APPEALS
2	FOR THE SECOND CIRCUIT
3	August Term, 2007
4 5 6	(Argued: November 8, 2007 Final Submission: April 7, 2009 Question Certified: March 17, 2010)
7	Docket No. 06-2071-cv
8	
9	JOHN GIORDANO,
10	<u>Plaintiff-Appellant</u> ,
11	- V -
12	MARKET AMERICA, INC., and THE CHEMINS COMPANY, INC.,
13	Defendants-Appellees.
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15	Before: McLAUGHLIN, CABRANES, and SACK, Circuit Judges.
16	Appeal from a judgment of the United States District
17	Court for the Southern District of New York (Jed S. Rakoff,
18	<u>Judge</u>) in a personal injury action alleging injuries resulting
19	from the ingestion of ephedra. The district court granted
20	summary judgment to the defendants on statute-of-limitations
21	grounds after concluding that the extended limitations period
22	provided by N.Y. C.P.L.R. § 214-c(4) was inapplicable to the
23	plaintiff's claim because his injuries were not caused by "latent
24	effects" of exposure to ephedra. We remanded the cause to the
25	district court to permit it to determine whether, for purposes of
26	N.Y. C.P.L.R. § 214-c(4), there was a genuine issue of material
27	fact for determination by a trier of fact as to whether

1	sufficient technical, scientific, or medical knowledge of the
2	cause of injury had been discovered, identified, or determined
3	during the original three-year limitations period for filing a
4	claim. Upon the court's response in the affirmative, the appeal
5	returned to us. Resolving it now requires answering three
6	separate questions of New York law, each of which has yet to be
7	addressed by New York courts and involves questions of public
8	policy that New York courts are better situated to resolve than
9	are we. We therefore certify the following three questions to
10	the New York Court of Appeals: (1) Are the provisions of N.Y.
11	C.P.L.R. § 214-c(4) providing for an extension of the statute of
12	limitations in certain circumstances limited to actions for
13	injuries caused by the latent effects of exposure to a substance?
14	(2) Can an injury that occurs within 24 to 48 hours of exposure
15	to a substance be considered "latent" for these purposes? (3)
16	What standards should be applied to determine whether a genuine
17	issue of material fact exists for resolution by a trier of fact
18	as to whether "technical, scientific or medical knowledge and
19	information sufficient to ascertain the cause of [the
20	plaintiff's] injury" was "discovered, identified or determined"
21	for N.Y. C.P.L.R. § 214-c(4) purposes?
22 23 24 25 26	BRIAN J. ISAAC, Pollack, Pollack, Isaac & De Cicco, <u>for</u> Sanders, Sanders, Block & Woycik, P.C. (Joseph B. Viener, <u>of</u> <u>counsel</u>), New York, NY, <u>for</u> <u>Plaintiff-Appellant</u> .
27 28 29	ANDREW ZAJAC, Fiedelman & McGaw, Jericho, NY, <u>for Defendant-Appellee</u> <u>Market America, Inc.</u>

Edward J. Stolarski, Jr., Wilbraham, 1 Lawler & Buba, Philadelphia, PA, for 2 Defendant-Appellee The Chemins Company, 3 4 Inc. 5 SACK, Circuit Judge: 6 Plaintiff John Giordano appeals from a judgment of the United States District Court for the Southern District of New 7 York (Jed S. Rakoff, Judge) in a personal injury action filed by 8 Giordano against defendants Market America, Inc., and The Chemins 9 10 Company, Inc. Giordano alleges that dietary supplements 11 containing the substance ephedra that the defendants supplied 12 caused his March 1999 cerebral aneurism and subsequent medical events. On April 10, 2006, the district court granted summary 13 14 judgment for the defendants on the grounds that Giordano's lawsuit, filed on July 28, 2003, was barred by the three-year 15 statute of limitations set forth in N.Y. C.P.L.R. § 214. See In 16 re Ephedra Prods. Liab. Litig., Nos. 04 M.D. 1598, 05 Civ. 1018, 17 2006 WL 944705, at *1, 2006 U.S. Dist. LEXIS 18691, at *1-2 18 (S.D.N.Y. Apr. 10, 2006) ("Ephedra II"). The court concluded 19 20 that the one-year extension of the statute of limitations 21 provided for in N.Y. C.P.L.R. § 214-c(4) for situations in which 22 the cause of the injury was not discovered during the original 23 three-year period to file suit was inapplicable because section 24 214-c(4) is limited to latent injuries and that injuries caused 25 by ephedra were not latent. Id. 2.6 The plaintiff appealed from the district court's

judgment and we heard oral argument on November 8, 2007. On

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- 1 August 18, 2008, we remanded for the limited purpose of asking
- 2 the district court to determine whether a genuine issue of
- 3 material fact existed as to whether an additional requirement of
- 4 N.Y. C.P.L.R. § 214-c(4) had been met, namely that Giordano
- 5 "allege and prove that technical, scientific or medical knowledge
- 6 and information sufficient to ascertain the cause of his injury
- 7 had not been discovered, identified or determined" prior to the
- 8 expiration of the otherwise applicable three-year statute of
- 9 limitations. See Giordano v. Mkt. Am., Inc., 289 F. App'x 467,
- 10 469 (2d Cir. 2008) (summary order). On February 24, 2009, in
- 11 response to our question and with expressed doubt as to the
- 12 standard to be applied under New York law, the district court
- 13 concluded that under any possible standard there was a genuine
- issue of material fact as to whether sufficient information had
- 15 been "discovered, identified or determined" at the relevant time.
- See In re Ephedra Prods. Liab. Litiq., 598 F. Supp. 2d 535, 537
- 17 (S.D.N.Y. 2009) ("Ephedra III").
- The applicability of N.Y. C.P.L.R. § 214-c(4) to
- 19 Giordano's claims is now before this Court again. The resolution
- of this issue requires us to answer three separate questions of
- New York law: (1) Are the provisions of N.Y. C.P.L.R. \S 214-c(4)
- 22 providing for an extension of the statute of limitations in
- certain circumstances limited to actions for injuries caused by
- 24 the latent effects of exposure to a substance?; (2) Can an injury
- 25 that occurs within 24 to 48 hours of exposure to a substance be
- considered "latent" for these purposes?; (3) What standards

- 1 should be applied to determine whether a genuine issue of
- 2 material fact exists for resolution by a trier of fact as to
- 3 whether "technical, scientific or medical knowledge and
- 4 information sufficient to ascertain the cause of [the
- 5 plaintiff's] injury" was "discovered, identified or determined"
- 6 for N.Y. C.P.L.R. § 214-c(4) purposes? Resolving the third
- 7 question requires us to decide both the level of certainty
- 8 required for knowledge to be deemed "sufficient to ascertain" the
- 9 cause of an injury, and the community that must possess this
- 10 knowledge -- that is, whether the knowledge must be reasonably
- 11 available to a plaintiff and his or her lawyers, or whether it
- must be reasonably available to the scientific, technical, or
- 13 medical community.
- In this instance, the district court found that "some
- 15 studies suggesting a possible connection between ephedra and
- 16 injuries similar to Giordano's were published in reputable
- 17 scientific journals that were publicly available" during the
- three-year period after discovery of Giordano's injury, but that
- 19 there was "a lack of awareness of the risks by even the most
- 20 interested members of the public" during that time. Ephedra III,
- 21 598 F. Supp. 2d at 537 n.1.
- The three questions of statutory interpretation raised
- by this appeal have not been answered conclusively by New York
- 24 courts. They, in turn, implicate questions of public policy
- 25 pertaining to how the New York Legislature intended to balance
- 26 the rights of those suffering personal injuries with the rights

- of defendants and with the need for judicial economy. New York
- 2 courts are better situated to answer these questions than are we.
- 3 We therefore certify them to the New York Court of Appeals.

4 BACKGROUND

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5 Pursuant to an order of the Judicial Panel on 6 Multidistrict Litigation, see 28 U.S.C. § 1407, the district 7 court that decided this case is charged with managing some 500 8 civil actions, including this one, involving claims of "personal 9 injury or wrongful death caused by dietary supplements containing ephedra." In re Ephedra Prods. Liab. Litiq., 393 F. Supp. 2d 10 11 181, 184 (S.D.N.Y. 2005) ("Ephedra I"). Ephedra is a plant 12 containing "ephedrine alkaloids." Id. at 185. Until relatively 13 recently, products containing ephedra were widely used by 14 consumers seeking "weight loss, increased energy and improved athletic performance." Id.; see also id. at 189 n.4. 15

The Food, Drug, and Cosmetic Act ("FDCA") prohibits

"[t]he introduction or delivery for introduction into interstate

commerce of any food . . . that is adulterated" 21

U.S.C. § 331(a). Section 402 of the FDCA provides that a "food

shall be deemed to be adulterated . . . [i]f it is a dietary

supplement or contains a dietary ingredient that . . . presents a

significant or unreasonable risk of illness or injury"

Id. § 342(f)(1)(A). On February 11, 2004, the United States Food

and Drug Administration ("FDA") effectively banned ephedra by

declaring dietary supplements containing ephedrine alkaloids

- 1 "adulterated" under the FDCA. See 21 C.F.R. § 119.1; Final Rule
- 2 Declaring Dietary Supplements Containing Ephedrine Alkaloids
- 3 Adulterated Because They Present an Unreasonable Risk ("FDA Final
- 4 Rule"), 69 Fed. Reg. 6788 (Feb. 11, 2004). This rule became
- 5 effective on April 12, 2004. <u>Id.</u>

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- The district court's opinion in Ephedra I granting in
- 7 part and denying in part motions to exclude expert testimony
- 8 pursuant to Rule 702 of the Federal Rules of Evidence and Daubert
- 9 v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993), provides
- 10 background regarding the alleged effects of ephedra.
- 11 According to the consolidated plaintiffs' experts:

[E]phedra can cause injury in susceptible people by increasing their blood pressure and heart rate. . . [A]n individual's blood pressure and heart rate normally vary over the course of a day, week and season, and . . . the effects of ephedra in an individual also vary over the course of the day in relation to when it was ingested and the individual's metabolism. If ephedra can sometimes be a contributing cause of heart attack, stroke, or sudden death in susceptible people, the injury might be triggered by the coincidence of peak events, such as transient peak blood pressure due to other causes occurring at the same time as peak ephedrine blood level. The longer the duration of repeated exposure, the more

likely such coincidence will occur.

Ephedra I, 393 F. Supp. 2d at 192 n.8.

According to the FDA:

People who use dietary supplements containing ephedrine alkaloids are at increased risk for serious adverse events, including heart attack, stroke, and death. Susceptible individuals (e.g., those with coronary artery disease or heart failure), many of whom may

not know they have underlying illnesses, are at increased risk for adverse events because these products can cause abnormal heart rhythms (pro-arrhythmic effect), even when the product is ingested at recommended doses over a short course (one or a few doses). Over longer periods of use, the risk for adverse health effects to the general population, including susceptible individuals, increases further due to a sustained elevation in blood pressure.

12 FDA Final Rule, 69 Fed. Reg. at 6825.

Before the district court, all parties

agree[d] that a recommended dose of a product containing ephedra . . . often raises the user's blood pressure and/or heart rate during the first few hours after ingestion, and they agree[d] that any increase maintained over years in a person's usual blood pressure or heart rate significantly increases the risk of cardiac injury and stroke.

Ephedra I, 393 F. Supp. 2d at 193-94 (emphasis omitted).

The district court also noted in its decision granting summary judgment to the defendants here that "ephedra acts within a few hours to cause a transitory elevation of blood pressure and heart rate and a temporary constriction of certain blood vessels." Ephedra II, 2006 WL 944705, at *1, 2006 U.S. Dist. LEXIS 18691, at *3-*4.

For approximately two years, ending on March 15, 1999,
Giordano used "ThermoChrome 5000," a dietary supplement
containing ephedra. Defendant-Appellee The Chemins Company,
Inc., manufactured ThermoChrome 5000; defendant-appellee Market

America, Inc., distributed it.

- 1 On March 15, 1999, Giordano suffered a cerebral
- 2 aneurysm. He underwent neurosurgery to repair it, but suffered
- 3 two strokes on March 17, 1999 -- two days later. He was left
- 4 with substantial cognitive, motor, and visual deficits.
- 5 Giordano's physicians were unable to determine the cause of the
- 6 aneurysm or the strokes.
- Nearly four years later, in February 2003, Giordano
- 8 became aware of news reports that the sudden death of
- 9 major-league baseball player Steve Bechler might have been linked
- 10 to his use of an ephedra-based dietary supplement. According to
- 11 Giordano's affidavit, these news reports were his first
- 12 indication that ThermoChrome 5000 may have been a cause of his
- 13 aneurysm and strokes.
- Some five months later, on July 28, 2003, Giordano
- 15 instituted this action in New York State Supreme Court. The
- 16 defendants removed it to the United States District Court for the
- 17 Southern District of New York on the basis of diversity of
- 18 citizenship. See 28 U.S.C. §§ 1332, 1441. They subsequently
- 19 moved for summary judgment on statute-of-limitations grounds. On
- 20 April 10, 2006, the district court granted the summary judgment
- 21 motions. Ephedra II, 2006 WL 944705, at *2, 2006 U.S. Dist.
- 22 LEXIS 18691, at *4. Giordano appealed.
- 23 After hearing argument on November 8, 2007, we remanded
- 24 pursuant to the procedures set forth in United States v.
- 25 <u>Jacobson</u>, 15 F.3d 19, 22 (2d Cir. 1994), for the limited purpose

of having the district court decide whether a genuine issue of material fact existed as to whether an additional requirement of N.Y. C.P.L.R. § 214-c(4) had been met, namely that the plaintiff "allege and prove that technical, scientific or medical knowledge and information sufficient to ascertain the cause of his injury had not been discovered, identified or determined" prior to the expiration of the otherwise-applicable three-year statute of limitations. See Giordano, 289 F. App'x at 469. Had the district court concluded that such knowledge had been discovered, identified or determined prior to the expiration of the otherwise-applicable statute of limitations, and had we affirmed on that issue on appeal, we would have been in a position to

affirm the district court's summary judgment without further

addressing the other questions raised on appeal.

apply, the district court answered this question in the affirmative under any standard. Ephedra III, 598 F. Supp. 2d at 537. It also suggested that, on further appeal, we might "want to consider certification to the [New York] Court of Appeals to sort this all out." Id. at 536-37. Lacking the authority itself to certify questions to the Court of Appeals, the district court was "bound to follow the interpretation of the Appellate Division in the absence of persuasive evidence that the New York Court of Appeals would rule differently if

presented with the issue," <u>id.</u> at 537, which the district court did.

The defendants now seek review of the district court's findings with respect to the existence of sufficient technical, scientific or medical knowledge to ascertain the cause of injury, and also seek affirmance of the district court's prior holding that N.Y. C.P.L.R. § 214-c(4) was inapplicable because ephedra did not cause any latent injuries. See Appellee Market America Ltr. Br. at 5-8 (filed Mar. 19, 2009); Appellee Chemins Co. Ltr. Br. at 1-5 (filed Mar. 20, 2009). In the alternative, the defendants seek certification of these issues to the New York Court of Appeals. See, e.g., Appellee Market America Ltr. Br. at 8.

Giordano, conversely, seeks affirmance of the district court's findings with respect to the existence of sufficient knowledge of causation, and reversal of the court's findings regarding latency. He opposes certification to the New York Court of Appeals at this time. See Appellant's Aff. in Opp. to Appellees' Ltr. Br. at 1-6 (filed Mar. 31, 2009). His preference for resolution of these issues without the further expenditure of time and money with an uncertain result is understandable.

22 DISCUSSION

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New York Civil Practice Law and Rules § 214-c(4) extends the statute of limitations for filing a personal injury claim in specified circumstances if the cause of injury was not and could not reasonably have been discovered during the three-

- 1 year period for filing a claim that is set forth in section
- 2 214(5). Applying section 214-c(4) to the facts at hand requires
- 3 answering three separate questions, the first of which is whether
- 4 section 214-c(4) is limited to injuries that are "latent."
- 5 Provided that the answer to that question is in the affirmative,
- 6 the second question is whether injuries caused by ephedra, which
- 7 are typically if not universally experienced within twenty-four
- 8 hours of its ingestion, are or may be "latent" for section 214-
- 9 c(4) purposes. If so, the third question is whether a genuine
- 10 issue of material fact exists for the trier of fact as to whether
- 11 technical, medical, or scientific knowledge sufficient to
- 12 ascertain the cause of Giordano's injury had been discovered,
- identified, or determined during the otherwise-applicable three-
- 14 year period. Each of these questions involves an issue of law
- 15 that has not previously been addressed by New York courts.
- In addressing the third question, we must take into
- account that "some studies suggesting a possible connection
- 18 between ephedra and injuries similar to Giordano's were published
- in reputable scientific journals that were publicly available"
- 20 during the three-year period after discovery of Giordano's
- 21 injury, but that there was "a lack of awareness of the risks by
- even the most interested members of the public" during that time.
- 23 Ephedra III, 598 F. Supp. 2d at 537 n.1.
- The third question is further complicated by two
- 25 ambiguities regarding the standard that should be used in
- answering it. First, it is unclear what level of certainty is

- 1 required for knowledge to be "sufficient to ascertain" the cause
- of an injury. Second, it is unclear what relevant group must
- 3 possess this knowledge, i.e., the plaintiff and his or her
- 4 lawyers, or the scientific, technical, or medical community.
- 5 I. Standard of Review
- "We review a district court's grant of summary judgment
- 7 de novo. Summary judgment is warranted only where, construing
- 8 all the evidence in the light most favorable to the non-movant
- 9 and drawing all reasonable inferences in that party's favor,
- 10 there is no genuine issue as to any material fact and the movant
- 11 is entitled to judgment as a matter of law." McBride v. BIC
- 12 <u>Consumer Prods. Mfg. Co.</u>, 583 F.3d 92, 96 (2d Cir. 2009)
- 13 (citations, internal quotation marks, and ellipsis omitted). The
- same standard applies whether summary judgment is granted on the
- 15 merits or on an affirmative defense such as the statute of
- limitations. See Buttry v. Gen. Signal Corp., 68 F.3d 1488, 1492
- 17 (2d Cir. 1995). Although summary judgment may, of course, be an
- appropriate means for disposing of an action that is barred by
- 19 the statute of limitations, it may not be granted if there is a
- 20 genuine issue of fact as to when the limitations period began or
- 21 expired and that fact is material to the question of whether the
- 22 statute has run. See BellSouth Telecomm., Inc. v. W.R. Grace &
- 23 Co.-Conn, 77 F.3d 603, 609 (2d Cir. 1996) (citing 10A Charles
- 24 Alan Wright et al., Federal Practice and Procedure § 2734, at
- 25 419, 421 (2d ed. 1983)).
- 26 II. New York's Statute of Limitations

- Because our subject-matter jurisdiction rests on 1 2 diversity of citizenship and Giordano's cause of action arose in 3 New York, we apply New York's substantive law and statute of limitations. See Guaranty Trust Co. v. York, 326 U.S. 99, 109-11 4 5 (1945); Stuart v. Am. Cyanamid Co., 158 F.3d 622, 626-27 (2d Cir. 1998), cert. denied, 526 U.S. 1065 (1999). 6 7 New York Civil Practice Law and Rules § 214 sets forth 8 the generally applicable limitations period for personal-injury 9 claims: "[A]n action to recover damages for a personal injury," 10 N.Y. C.P.L.R. § 214(5), "must be commenced within three years," id. § 214, "except as provided in[, inter alia,] section[] 214-11 12 c," id. § 214(5). Two provisions of section 214-c are relevant here. 13 14 Section 214-c(2) provides: 15 Notwithstanding the provisions of section 16 214, the three year period within which an 17 action to recover damages for personal injury or injury to property caused by the latent 18 effects of exposure to any substance or 19 combination of substances, in any form, upon 20 21 or within the body or upon or within property 22 must be commenced shall be computed from the date of discovery of the injury by the 23 24 plaintiff or from the date when through the
 - Id. § 214-c(2). Section 214-c(4) provides:

whichever is earlier.

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Notwithstanding the provisions of subdivisions two and three[1] of this

exercise of reasonable diligence such injury

should have been discovered by the plaintiff,

 $^{^{1}}$ Section 214-c(3) applies to claims, unlike this one, in which the law requires a "notice of claim [to] be filed or presented within a specified period." N.Y. C.P.L.R. § 214-c(3). It is not relevant to this action.

section, where the discovery of the cause of the injury is alleged to have occurred less than five years after discovery of the injury or when with reasonable diligence such injury should have been discovered, whichever is earlier, an action may be commenced or a claim filed within one year of such discovery of the cause of the injury; provided, however, if any such action is commenced or claim filed after the period in which it would otherwise have been authorized pursuant to subdivision two or three of this section the plaintiff or claimant shall be required to allege and prove that technical, scientific or medical knowledge and information sufficient to ascertain the cause of his injury had not been discovered, identified or determined prior to the expiration of the period within which the action or claim would have been authorized and that he has otherwise satisfied the requirements of subdivisions two and three of this section.

24 Id. $\leq 214-c(4)$.

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It is undisputed that Giordano did not commence litigation within three years of being exposed to ephedra, and that his suit was thus not commenced within the general limitations period provided by section 214. He ingested the product containing ephedra for two years up to and likely including March 15, 1999. He did not file suit, however, until July 28, 2003, more than three but less than five years later.

Moreover, Giordano's claim is not covered by section 214-c(2) because he did not assert it within three years of discovering the injury alleged to have been caused by ephedra —the aneurysm, which occurred on March 15, 1999, and the strokes, which occurred two days thereafter. The question for us, then, is whether section 214-c(4), which in certain circumstances

- 1 provides for a one-year limitations period running from the date
- of discovery of the cause of an injury, saves Giordano's claim.
- 3 Because section 214-c and its subsections provide
- 4 exceptions to the general statute of limitations, Giordano bears
- 5 the burden of showing that one of the exceptions applies to his
- 6 claim. See Bano v. Union Carbide Corp., 361 F.3d 696, 710 (2d
- 7 Cir. 2004); <u>Burger v. Union Carbide Corp.</u>, 304 A.D.2d 700, 701,
- 8 758 N.Y.S.2d 381, 383 (App. Div. 2003) (per curiam).
- 9 III. The District Court's Decisions
- The district court granted summary judgment to the
- 11 defendants based on its conclusion that the foregoing exceptions
- 12 to New York's three-year statute of limitations did not apply.
- 13 Ephedra II, 2006 WL 944705, at *1, 2006 U.S. Dist. LEXIS 18691,
- 14 at *4.
- The court determined at the outset that New York courts
- do not allow equitable tolling of the three-year statute of
- 17 limitations. Id., 2006 WL 944705, at *1, 2006 U.S. Dist. LEXIS
- 18 18691, at *2-*3 (citing In re N.Y. County DES Litig., 89 N.Y.2d
- 19 506, 511, 678 N.E.2d 474, 477, 655 N.Y.S.2d 862, 865 (1997)).
- 20 Consequently, any extension of or exception to the statute of
- 21 limitations must be found in section 214-c. Id. Giordano does
- 22 not take issue with this conclusion.
- The district court then noted that section 214-c(2),
- but not section 214-c(4), expressly applies only to injuries
- caused by the "latent effects" of exposure to a substance.
- Despite the absence of the term "latent effects" in section 214-

- 1 c(4), the section governing discovery of the cause of injury more
- 2 than three but less than five years after discovery of the
- 3 injury, the district court concluded that that section is also
- 4 limited to injuries caused by "latent effects." The district
- 5 court's conclusion was based primarily on the several references
- in section 214-c(4) to section 214-c(2), the section containing
- 7 the latent effects language. Id., 2006 WL 944705, at *1, 2006
- 8 U.S. Dist. LEXIS 18691, at *3 (citing Bano, 361 F.3d at 709).
- 9 The district court then concluded as a matter of law,
- 10 based on the undisputed evidence before it, that ephedra's
- 11 alleged effects on Giordano were not "latent." First, the court
- observed that Giordano "discovered his stroke immediately upon
- 13 its occurrence." <u>Id.</u>, 2006 WL 944705, at *1, 2006 U.S. Dist.
- 14 LEXIS 18691, at *3. Second, the court noted that the evidence
- admitted at the Daubert hearings in the consolidated cases showed
- that ephedra's effects were short-term, usually occurring within
- 17 a few hours of ingestion. Id., 2006 WL 944705, at *1, 2006 U.S.
- 18 Dist. LEXIS 18691, at *3-4. The district court reasoned that
- 19 "[t]o hold § 214-c applicable to a stroke allegedly caused by
- 20 ephedra would effectively eliminate the statute's limitation to
- 21 'latent effects.'" Id., 2006 WL 944705, at *1, 2006 U.S. Dist.
- 22 LEXIS 18691, at *4.
- 23 Rather than decide the latency question unnecessarily,
- 24 we remanded with instruction to the district court to determine
- 25 "whether there is a genuine issue of material fact as to whether
- 26 sufficient scientific or medical knowledge was available to

- 1 Giordano such that he could have ascertained the cause of his
- 2 injury prior to the expiration of the three-year limitations
- 3 period provided by section 214-c(2)." Giordano, 289 Fed. App'x
- 4 at 469.
- In answering this question in the affirmative, the
- 6 district court recognized two separate ambiguities in the statute
- 7 and, as noted, suggested that certification to the New York Court
- 8 of Appeals -- an approach not available to the district court --
- 9 might be appropriate. Ephedra III, 598 F. Supp. 2d at 536-37.
- 10 First, the court viewed the statute as ambiguous as to
- 11 whether sufficient knowledge to "ascertain" the cause of an
- injury requires certainty as to the cause, as suggested by the
- dictionary definition of the term, or requires "something akin to
- 14 finding a probable connection," which the court understood to be
- 15 the way in which the New York Appellate Division, Third
- 16 Department, had construed the term. Id. at 536.
- 17 Second, the district court viewed the statute to be
- ambiguous as to "precisely who has to know what before § 214-c
- 19 applies." Id. at 537 n.1. The court was unable to determine
- from the face of the statute whether the knowledge of the cause
- of injury needed to be reasonably available to the scientific and
- 22 medical communities or reasonably available to the plaintiff.
- 23 Id. The court recognized that some studies did exist linking
- 24 ephedra to injuries similar to Giordano's as early as 1996, but
- 25 also observed that most lawsuits related to these studies were
- 26 not filed until after 2002, "suggesting, at least, a lack of

- 1 awareness of the risks by even the most interested members of the
- 2 public prior to that time." <u>Id.</u>
- 3 Despite these problematic aspects of the statute, the
- 4 district court found a genuine issue of material fact as to
- 5 whether the requisite knowledge existed because "there are
- 6 genuine issues of material fact remaining to be resolved on
- 7 virtually any view one takes of the meaning of \$ 214-c(4)." Id.
- 8 at 537.
- 9 IV. Analysis
- 10 A. "Latent Effects"
- 1. The Presence of a Latency Requirement in Section
- 12 214-c(4).
- We find insufficient guidance in the text of section
- 14 214-c(4), its legislative history, and the New York State case
- law interpreting it to decide whether there is an implied
- requirement that injuries be latent in order for the provision to
- 17 apply.
- There is indeed support for the district court's
- 19 conclusion that section 214-c(4) is limited to injuries caused by
- 20 the "latent effects" of exposure even though that subsection does
- 21 not expressly use those words. The proviso clause of section
- 22 214-c(4) permits an action to be brought if it is
- "commenced . . . after the period in which it would otherwise
- have been authorized pursuant to [section 214-c(2)]" and requires
- 25 the plaintiff to demonstrate that "he has otherwise satisfied the
- 26 requirements of [section 214-c(2)]." N.Y. C.P.L.R. § 214-c(4).

exposure" to ephedra, N.Y. C.P.L.R. § 214-c(2), then the terms of section 214-c(2) were never applicable to him: His action would

If Giordano's injuries were not "caused by the latent effects of

- 4 not "otherwise have been authorized pursuant to [section 214-
- 5 c(2)]" and he cannot be said to have "otherwise satisfied the
- 6 requirements [of section 214-c(2)]." Id. \S 214-c(4).
- 7 But there are persuasive arguments to the contrary.
- 8 Latency was expressly made a requirement in section 214-c(2) but
- 9 omitted from section 214-c(4). As these sections are drafted in
- largely parallel fashions, with the first relating to discovery
- of an injury and the second relating to discovery of the cause of
- an injury, we find it plausible that this omission was
- 13 intentional.

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- The notion that the legislature intentionally omitted
 this requirement is consistent with the differing purposes of the
 subsections. Section 214-c(2) governs injuries that are not
 discovered until after the three-year statute of limitations. A
- 18 requirement of latency serves a limiting purpose by eliminating
- 19 claims where the injury could have been but was not discovered,
- and in so doing places an added onus on the plaintiff to comply
- 21 with the otherwise-applicable statute of limitations by timely
- 22 prosecuting actions based on injuries that are discoverable.
- Were this requirement not in the statute, courts would presumably
- 24 be forced to decide cases in which there was a dispute over
- whether a plaintiff was reasonably diligent in discovering an
- 26 injury. By adding a latency requirement, courts are provided

- 1 with more of a bright-line rule that serves the purpose of
- 2 promoting judicial economy while nonetheless permitting suit to
- 3 be brought in some circumstances for injuries that were not
- 4 discoverable within the three-year time period.
- 5 Section 214-c(4), on the other hand, governs injuries
- 6 whose causes could not have been reasonably known during the
- 7 otherwise-applicable three-year time period for filing a claim.
- 8 In these cases, a requirement of latency does not promote the
- 9 diligent prosecution of claims. The question under section 214-
- 10 c(4) is whether sufficient information was available regarding
- 11 the cause of an injury to reasonably expect the plaintiff to have
- 12 taken timely legal action. Whether the injury was latent or
- patent is irrelevant to the answer. In contrast to the latency
- requirement of section 214-c(2), which prods plaintiffs to be
- diligent in discovering injuries, a latency requirement would
- 16 have little effect on the purposes of section 214-c(4) inasmuch
- as it has little impact on the diligence with which plaintiffs
- 18 make themselves aware of scientific information concerning the
- 19 cause of an injury.
- The New York Court of Appeals is, in our view, the
- 21 appropriate judicial body to decide, if it chooses to do so,
- 22 whether there is an implicit latency requirement in section 214-
- c(4), because the decision requires an analysis of the
- legislative history, intent of the legislature, and broader
- 25 purposes of that section.

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2. The Latency of Ephedra.

Even were there a latency requirement, we are not 1 2 entirely persuaded that the purported effects of ephedra are not "latent" within the meaning of section 214-c. The district court relied upon our comment in Bano that "[s]ection 214-c modifies § 214 with respect to a claimed injury that was not discoverable 6 immediately upon its occurrence," Bano, 361 F.3d at 709, to conclude that because Giordano "discovered his stroke immediately 8 upon its occurrence," his injury was not a latent effect of ephedra. Ephedra II, 2006 WL 944705, at *1, 2006 U.S. Dist. 9 LEXIS 18691, at *3. The claimed injuries in this case -- the 10 aneurism and strokes² -- were, as the district court noted, 11 12 immediately discoverable when they occurred. But section 214-c refers not to a latency period between injury and its discovery, 13 but to "personal injury . . . caused by the latent effects of 14 15 exposure." N.Y. C.P.L.R. § 214-c(2). In Giordano's case, expert 16 testimony indicates that the effects of exposure to ephedra may not have manifested themselves for hours. The fact that the 17 18 effects of the exposure -- the aneurysm and strokes -- were 19 discoverable immediately upon their occurrence do not appear to 20 us to matter. The proper question, we think, is whether ephedra's effects were "latent." 21

Under section 214-c, the term "injury" refers to the manifestation of the harmful effects of exposure to a substance, not the exposure itself. See Sweeney v. Gen. Printing Inc., 210 A.D.2d 865, 865, 621 N.Y.S.2d 132, 133 (App. Div. 1994) ("The wording of CPLR 214-c makes clear that the injury to which it refers is distinct from the actual exposure to the harmful substance, for the injury is, by definition, caused by the latent effects of that exposure, and consequently must be something that occurs later." (citation omitted)).

1 Addressing this question, the district court observed:

[R]esearchers in a study of ephedra and stroke admitted into evidence during the <u>Daubert</u> hearings did not consider stroke patients to have been relevantly exposed to ephedra unless they used it within three days before their stroke; indeed, because of ephedra's short-acting properties, the researchers studied strokes that occurred within 24 hours after using ephedra.

Ephedra II, 2006 WL 944705, at *1, 2006 U.S. Dist. LEXIS 18691, at *4. The court compared the time lapse of "a few weeks" between exposure and manifest injury in Bano, where we treated the injury as latent, Bano, 361 F.3d at 709-10, with the time lapse between exposure to ephedra and manifest injury, which appears to be one day, more or less. The district court decided that the "few weeks" before manifestation of injury in Bano rendered the effect "latent" whereas the approximately twenty-four hours in the present case did not. Ephedra II, 2006 WL 944705, at *1, 2006 U.S. Dist. LEXIS 18691, at *4.

But nothing in the text of section 214-c suggests to us that a relatively short period of latency, such as the likely period of time between Giordano's exposure to the ephedra that allegedly caused his injury and the manifestation of the injury itself, is insufficient to invoke section 214-c(4). The statute, we assume for this purpose, requires that Giordano's injury be caused by the "latent effects" of exposure to ephedra, but says nothing about the time period that must elapse between exposure and manifestation of injury in order for the effects of exposure to be considered "latent."

1 Dictionary definitions of "latent" are, not

2 surprisingly, many and various. In substance, however, they

3 seem uniformly to treat "latent" as a term referring to a thing

4 or condition that is present but not evident or manifest.

5 Although the period of time between exposure and the

6 manifestation of injury was relatively short in Giordano's case,

it was nonetheless a period of time in which ephedra was present

8 in Giordano's body, but its effects were not evident or manifest.

The language of the statute thus suggests that the purported

10 effects of ephedra may, at least, be "latent," and that section

11 214-c may therefore be applicable.

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Looking to the legislative purpose for the enactment of section 214-c as part of New York's 1986 tort reform package, the New York Court of Appeals has observed that one "goal of the Legislature in adopting CPLR 214-c was to provide relief to injured New Yorkers whose claims would otherwise be dismissed for untimeliness simply because they were unaware of the latent injuries until after the limitations period had expired." N.Y. County DES Litig., 89 N.Y.2d at 513-14, 678 N.E.2d at 478, 655 N.Y.S.2d at 866 (citations and internal quotation marks omitted).

They include "Concealed; dormant," <u>Black's Law Dictionary</u> 898 (8th ed. 2004); "Present or potential but not evident or active," <u>The American Heritage Dictionary of the English Language</u> 961 (9th ed. 2009); "Hidden, concealed . . .; present or existing, but not manifest, exhibited, or developed," 8 <u>The Oxford English Dictionary</u> 680-81 (2d ed. 1989); and "[E]xisting in hidden, dormant, or repressed form but usually capable of being evoked, expressed, or brought to light: existing in posse: not manifest," <u>Webster's Third New International Dictionary of the English Language Unabridged</u> 1275 (2002).

- 1 But in addition to seeking to toll the time period between
- 2 exposure and manifestation of injury, "the Legislature [also]
- 3 anticipated and made specific provision for the problem that
- 4 arises when the plaintiff has discernable bodily symptoms but the
- 5 toxic etiology of those symptoms has not yet been discovered."
- 6 Id. at 512, 678 N.E.2d at 477, 655 N.Y.S.2d at 865.
- 7 Thus, it appears likely to us that by enacting section
- 8 214-c, the New York legislature sought to address both situations
- 9 in which injury is not evident immediately upon exposure to a
- 10 harmful substance and situations in which the cause of physical
- 11 symptoms cannot be discovered within the otherwise-applicable
- 12 limitations period. In light of these dual goals, we see no
- 13 reason why Giordano is not entitled to prove that his injury was
- caused by the "latent effects" of his exposure to ephedra such
- that he may invoke section 214-c(4)'s one-year limitation period
- 16 running from his alleged discovery that ephedra was its cause.
- 17 Rather than make a definitive decision on this
- 18 difficult issue of New York law, however, we certify it to the
- 19 New York Court of Appeals.
- 20 B. Technical, Scientific, or Medical Knowledge Requirement
- Even if Giordano surmounts whatever "latency" barriers
- 22 his invocation of section 214-c(4) may face, to withstand the
- 23 motion for summary judgment, he must also establish a genuine
- 24 issue of material fact for the trier of fact to decide as to
- 25 whether "technical, scientific or medical knowledge and
- 26 information sufficient to ascertain the cause of his injury had

- 1 not been discovered, identified or determined" prior to the
- 2 expiration of the three-year limitations period that would
- 3 otherwise run from the date of discovery of his injury as
- 4 provided in section 214-c(4). The district court found this
- 5 requirement satisfied even though it expressed serious doubt as
- 6 to what standard it should use in evaluating whether the
- 7 knowledge or information in question was "sufficient to
- 8 ascertain" the cause of the injury. That is, the district court
- 9 expressed its doubt as to both what level of certainty the
- 10 knowledge or information had to be established, and who was
- 11 required to possess the knowledge or information. Ephedra III,
- 12 598 F. Supp. 2d at 536-37.
- Discussing the level of certainty required by the
- 14 statute, the district court observed an ambiguity as to whether
- sufficient knowledge to "ascertain" the cause of an injury
- requires certainty as to cause, as suggested by the dictionary
- definition of the term, or, alternatively, "something akin to
- 18 finding a probable connection," which the court understood to be
- 19 the way in which the New York Appellate Division, Third
- Department, had construed the term. Id. at 536 (citing Pompa v.
- 21 Burroughs Wellcome Co., 259 A.D.2d 18, 24-25, 696 N.Y.S.2d 587,
- 22 592 (App. Div. 1999)). Addressing the question of who was
- required to attain this certainty, the court found the statute
- 24 ambiguous as to whether the knowledge or information in question
- 25 needed to be reasonably available to the scientific and medical
- communities, or reasonably available to the plaintiff and his or

- 1 her lawyers. Id. at 537 n.1 (seeking guidance on "precisely who
- 2 has to know what before § 214-c applies"). Nevertheless, the
- 3 district court held that there was a genuine issue of material
- 4 fact as to whether sufficient knowledge existed under any
- 5 standard. Id. at 537.
- 6 The district court made two findings that render the
- 7 standard applied relevant to the outcome of the question of
- 8 sufficient knowledge. On the one hand, the court found that some
- 9 studies did exist linking ephedra to injuries similar to
- 10 Giordano's as early as 1996. <u>Id.</u> at 537 n.1. On the other hand,
- 11 it noted that most lawsuits related to these studies were not
- 12 filed until after 2002, "suggesting, at least, a lack of
- awareness of the risks by even the most interested members of the
- 14 public prior to that time." Id. Under this set of facts, the
- 15 standard applied could affect the outcome of this case in
- 16 multiple ways.
- With regard to who must possess the knowledge, if the
- statute requires that knowledge of causation must be reasonably
- available to the <u>scientific community</u>, then sufficient knowledge
- 20 may have been available as early as 1996, rendering section 214-
- c(4) inapplicable to Giordano. If, however, the standard is that
- knowledge of causation be reasonably available to the plaintiff
- and his or her lawyers, then the district court's finding that
- 24 most related lawsuits were filed after 2002 may create a genuine
- issue of fact as to whether the knowledge in question was

- reasonably available during the three-year period following injury and section 214-c(4) may apply.
- 3 As to the requisite standard of certainty, studies
- 4 suggesting the relevant causal link between ephedra and the
- 5 injuries it causes began to appear in 1996, the FDA banned it in
- 6 2004, and no study has yet confirmed that ephedra causes injuries
- 7 similar to those suffered by Giordano. See Ephedra I, 393 F.
- 8 Supp. 2d at 192-96. In light of these facts, if the standard is
- 9 that information suggesting causation be available, then the
- information may have been available as early as 1996 and
- 11 Giordano's claim may be time-barred. If the standard is that
- information arguably constituting scientific proof of causation
- 13 be available, then the question is more difficult and later
- 14 studies or the timing of the FDA's ban may mean the information
- was available at a later date, in which case Giordano's claims
- may or may not be time-barred. If the standard tracks the plain
- meaning of the statute and requires that sufficient information
- 18 to "ascertain" the cause of injury be reasonably available, then
- 19 the fact that studies have still not conclusively proven that
- 20 ephedra causes injuries similar to Giordano's may make section
- 21 214-c(4) inapplicable for that reason.
- 22 Although we have in the past attempted to interpret the
- intention of the New York Legislature in this regard, we have not
- done so definitively. <u>See, e.g., Freier v. Westinghouse Elec.</u>
- 25 Corp., 303 F.3d 176, 207 (2d Cir. 2002), cert. denied, 538 U.S.
- 998 (2003) (observing that the New York Legislature likely

- 1 "intended CPLR § 214-c(4) to refer only to scientific knowledge
- that was 'reasonably available' to the plaintiff"). In Freier,
- 3 we recognized that the meaning of "discovered, identified or
- 4 determined" for the purposes of section 214-c(4) was far from
- 5 clear. <u>Id.</u> at 206 ("[I]s 'scientific knowledge' 'discovered'?
- 6 Is 'scientific knowledge' 'determined' -- and if so, does the
- 7 word 'determined' connote a consensus?"). We therefore look to
- 8 the New York Court of Appeals for guidance.
- 9 V. Certification to the New York Court of Appeals
- The local rules of the Second Circuit provide that
- "[i]f state law permits, the court may certify a question of
- 12 state law to that state's highest court." 2d Cir. R. 27.2; see
- 13 <u>also Prats v. Port Auth. of N.Y. & N.J.</u>, 315 F.3d 146, 150-51 (2d
- 14 Cir. 2002). Certification to the New York Court of Appeals is
- discretionary, see McCarthy v. Olin Corp., 119 F.3d 148, 153 (2d
- 16 Cir. 1997), but we have recognized at least four factors as
- 17 relevant in guiding that discretion.
- 18 First, we have decided certification to be appropriate
- where the New York Court of Appeals has not spoken clearly on an
- issue and we are unable to predict, based on other decisions by
- New York courts, how the Court of Appeals would answer a certain
- question. See Kuhne v. Cohen & Slamowitz, LLP, 579 F.3d 189, 198
- 23 (2d Cir. 2009); O'Mara v. Town of Wappinger, 485 F.3d 693, 698
- 24 (2d Cir. 2007). We have found no conclusive precedents to answer
- 25 the three questions certified here.

- 1 Second, we have concluded that certification is
- 2 appropriate where the "statute's plain language does not indicate
- 3 the answer." Riordan v. Nationwide Mut. Fire Ins. Co., 977 F.2d
- 4 47, 51 (2d Cir. 1992); accord Colavito v. N.Y. Organ Donor
- 5 Network, Inc., 438 F.3d 214, 229 (2d Cir. 2006). Here, the plain
- 6 meaning of the statute does not definitively answer any of the
- 7 three questions certified. Latency is not explicit in the text
- 8 of N.Y. C.P.L.R. \S 214-c(4), nor does section 214-c(2), which
- 9 does include an explicit latency requirement, sufficiently define
- 10 the term to apply it to the effects of ingesting ephedra.
- 11 Similarly, it is not clear from the text of section 214-c(4) what
- 12 level of certainty is required or what group is implicated by the
- 13 subsection's requirement that sufficient knowledge exist to
- 14 ascertain the cause of the injury. This factor therefore
- 15 supports certification.
- 16 Third, we have thought certification to be appropriate
- 17 where the decision reflects value judgments and important public
- 18 policy choices that the New York Court of Appeals is better
- 19 situated than we are to make. See Colavito, 438 F.3d at 229;
- Blue Cross & Blue Shield of N.J., Inc. v. Phillip Morris USA,
- 21 Inc., 344 F.3d 211, 221 (2d Cir. 2003). The policy questions at
- issue here directly implicate the New York Legislature's desire
- 23 to balance, inter alia, a victim's ability to recover for his or
- her damages, a defendant's ability to live free from fear of
- 25 litigation, and judicial economy. By enacting section 214-c(4),
- 26 the New York Legislature created a limited exception to the

- 1 general rule that personal injury cases be brought within three
- 2 years. The New York Court of Appeals has more familiarity with
- 3 and is more competent to interpret the boundaries of that
- 4 exception.

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- 5 The three questions certified are central to the
- 6 outcome of this case, inasmuch as each is a hurdle that Giordano
- 7 must overcome in order for section 214-c(4) to apply and his
- 8 action to be timely, and resolution of each depends upon the
- 9 guidance we now seek from the New York Court of Appeals.
- The balance of these factors therefore militates in
- 11 favor of certification in this case.
- 12 CONCLUSION
- For the foregoing reasons, we certify the following three questions to the New York Court of Appeals:
- 1. Are the provisions of N.Y. C.P.L.R. § 214-c(4)

 providing for an extension of the statute of

 limitations in certain circumstances limited to

 actions for injuries caused by the latent effects
 - of exposure to a substance?
 - 2. Can an injury that occurs within 24 to 48 hours of exposure to a substance be considered "latent" for these purposes?
 - 3. What standards should be applied to determine whether a genuine issue of material fact exists for resolution by a trier of fact as to whether "technical, scientific or medical knowledge and

information sufficient to ascertain the cause of

[the plaintiff's] injury" was "discovered,

identified or determined" for N.Y. C.P.L.R. § 214
c(4) purposes?

With respect to the last question, we especially seek guidance that will enable us to answer the question of whether sufficient knowledge exists to ascertain a cause of injury where "some studies suggesting a possible connection between ephedra and injuries similar to [the plaintiff's] were published in reputable scientific journals that were publicly available" during the three-year period after the discovery of the plaintiff's injury, but where there was "a lack of awareness of the risks by even the most interested members of the public" during that time. Ephedra III, 598 F. Supp. 2d at 537 n.1.

In formulating three specific questions for certification we do not intend to limit the scope of the Court of Appeals' analysis and we invite the Court of Appeals to expand upon or alter these questions as it should deem appropriate. See Kirschner v. KPMG LLP, 590 F.3d 186, 195 (2d Cir. 2009).

Pursuant to New York Court of Appeals Rule 500.27 and United States Court of Appeals for the Second Circuit Rule 27.2, it is hereby ORDERED that the Clerk of this Court transmit to the Clerk of the Court of Appeals of the State of New York this opinion as our certificate, together with a complete set of the briefs, appendix, and record filed in this Court by the parties. We direct the parties to bear equally any fees and costs that may

- 1 be imposed by the New York Court of Appeals in connection with
- 2 this certification. This panel will retain jurisdiction of the
- 3 appeal after disposition of this certification by the New York
- 4 Court of Appeals.