IN THE SUPREME COURT OF FLORIDA

CARTER GRADY and
MILDRED GRADY,

Petitioners,

v.

BROWN & WILLIAMSON TOBACCO CO., as successor by merger to The American Tobacco Co.,

Respondent.
_____/

CASE NO.: 94,797
1ST DCA CASE NO.: 96-4831

AMICUS CURIAE BRIEF OF DES ACTION

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STATEMENT OF THE CASE AND FACTS

Amicus curiae DES Action adopts the Statement of the Case and Facts found in the Petitioner's Initial Brief on the Merits. For purposes of this brief, the relevant facts are as follows:

Grady Carter began smoking Lucky Strike cigarettes, manufactured by Brown & Williamson's predecessor[1] in 1947. In 1972, he switched to another brand, manufactured by a different company.

Mr. Carter began to spit up blood on January 29, 1991. On checking a home medical reference book, he found that this could be caused by tuberculosis or by cancer. Mr. Carter had been exposed to tuberculosis at the workplace. He immediately quit smoking. He also immediately made an appointment to see a physician. Mr. Carter saw doctors on February 4 and on February 5. The February 5 medical notes list a number of impressions, including left upper lung nodule, COPD, chronic bronchitis, a history of nephrolithiasis (a kidney disease), previous history of ulcer disease, and cigarette smoking 65 pack years. Neither "cancer" nor "tumor" was explicitly mentioned in the notes.

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[1]Two weeks after this case was filed, American Tobacco Company (which manufactured Lucky Strikes) merged into Brown and Williamson, which answered the Complaint as American Tobacco Company's "successor by merger". For ease of reference, we refer only to Brown & Williamson.

On February 5, Mr. Carter was told by his physician that the left lung nodule could be tuberculosis, or it could be a slowly resolving pneumonia, or it could be cancer. The doctor deliberately chose to mention cancer last. The doctor told Mr. Carter that further testing was required in order to determine what the cause of the condition was.

Mr. Carter promptly made arrangements for those further tests, which were conducted on February 12. On February 14, Mr. Carter was told that he did, in fact, have cancer.

Since 1964, cigarette makers have been required to place a warning label on each pack of cigarettes. From 1964 to 1969, that required warning was: "CAUTION: CIGARETTE SMOKING MAY BE HAZARDOUS TO YOUR HEALTH." In 1969, the statute was amended in several ways. First, it required that a stronger warning be given: "WARNING: THE SURGEON GENERAL HAS DETERMINED THAT CIGARETTE SMOKING IS HAZARDOUS TO YOUR HEALTH". Secondly, a stronger preemption clause was added to the statute. Finally, the warning label requirement was extended to include all advertising and promotion of cigarettes. In 1984, the statute was further amended to require four rotating warnings.

This action was filed on February 10, 1995. It alleged liability in one count of negligence, including failure to give

adequate warning of smoking hazards, and a second count of strict liability, alleging that the "Lucky Strike" product was unreasonably dangerous due both to failure to warn and design defects. Brown & Williamson asserted the statute of limitations as an affirmative defense, but the trial court ruled that there were factual questions as to when the cause of action had accrued, and that those issues must be determined by the jury.

During the course of trial, Mr. Carter adduced evidence of various warnings which could have been given, but were not. Brown & Williamson took the position, both before and during trial, that (1) there was no reliable evidence that cigarette smoking caused cancer and (2) cigarettes were not addictive. Brown & Williamson objected to evidence as to the various warnings on the basis that the 1969 Act preempted all liability under state tort law in connection with warnings in advertising and promotion after its effective date. Those objections were overruled.

Following a lengthy trial, the jury found Brown & Williamson liable and specifically found that the cause of action had not accrued more than four years prior to filing of the complaint.

After judgment was entered and post trial motions ruled on, Brown & Williamson appealed to the First District Court of Appeal. That court ruled (723 So.2d at 836) that the facts of this case unquestionably showed that the accumulated effects of smoking manifested themselves to Grady Carter more than four years before he filed suit, and accordingly that reversal was required based on the statute of limitations. The First District further held that the trial references to other potential warnings required a reversal in light of the federal preemption of causes of action based on adequacy of warning labels on cigarette packaging after

1969. *Id*.

Following motions for rehearing, Petitioner timely invoked this Court's discretionary review jurisdiction based on express and direct conflict under Article V, Section 3(b)(3), Florida Constitution. This Court accepted jurisdiction and established a briefing schedule.

SUMMARY OF ARGUMENT

Although Carter knew he had a medical problem on January 29, 1991, he had reason to believe that it was not one connected with cigarette smoking. His home medical reference and his doctor both indicated that it might be tuberculosis, to which he had been exposed. On February 5, he was told it might be cancer, tuberculosis, or pneumonia, and that further testing was required to determine what the condition was. The medical notes of that date list several "impressions," but not any causal relationship to cigarettes. Only on February 14, when he was definitively diagnosed with cancer, did Carter have the requisite knowledge to start the running of the statute of limitations.

A tentative diagnosis, no matter how correct it turns out to be, is not enough to start the statutory clock, especially where there is reason to believe that the condition is one which is not connected to the product. Even if the medical notes had

established a causal connection, their contents should not be imputed to Carter, since he acted with due diligence in determining the cause of his condition.

Even if Carter had sufficient knowledge, more than four years prior to filing suit, of his COPD, that should not bar his separate claim for cancer. Where a product can cause two unrelated diseases in the same person at different times, the person has two separate causes of action, not one. A contrary result would encourage otherwise - unnecessary litigation and lead to both inadequate and excessive damage awards.

Federal law may preempt state law, but the scope of preemption is narrowly construed, especially where the federal law impinges on areas within the traditional province of the states. The trial court in this case followed controlling precedent from the Supreme Court of the United States in instructing the jury. It is the Evidence Code, not federal preemption doctrine, that governs the admissibility of evidence. Thus, evidence which might have supported a failure to warn claim (had such a claim not been preempted) is admissible if it is relevant to some other issue in the case. Federal preemption doctrine deals with issue preclusion, not with admissibility of evidence.

I. INTEREST OF THE AMICUS CURIAE

Amicus Curiae is a non-profit organization with several thousand members. Its purposes include disseminating information about the effects of the drug diethylstilbestrol (hereafter "DES") upon people who were exposed to the drug *in utero*. As this court noted in *Conley v. Boyle Drug Company*, 570 So.2d 275, 279 N.1 (Fla. 1990), DES was first marketed in 1941, and was approved for use in preventing miscarriages in 1947. It continued to be produced and marketed for that purpose until 1971, when medical researchers established a possible link between exposure to DES while *in utero* and the development in young women of a form of cancer known as clear cell adenocarcinoma. *id*. Up to 300 companies may have marketed DES between 1947 and 1971. *id.*, N. 2.

In addition to causing clear cell adenocarcinoma, DES has since been implicated in reproductive and infertility problems of children of DES mothers, and in the development of testicular cancer in sons of DES mothers, and it may be implicated in causing other adverse medical conditions. Thus, just as cigarette smoking can cause two separate and distinct injuries (for instance, COPD and lung cancer), DES can likewise cause a single individual different problems (such as infertility problems and clear cell adenocarcinoma) which manifest themselves at different times.

Additionally, the Food and Drug Administration required

certain information to accompany DES and, as with federal legislation on cigarettes, contains a preemption clause. Thus, as to the limitation of actions issue and the preemption issue, children of DES mothers find themselves in potentially the same situation as Mr. Carter. Like cigarettes, the adverse medical conditions caused by DES only appear after a very long period. Like cigarettes, DES can cause different injuries at different times to the same person. Thus, children of DES mothers have a strong interest in the resolution of the limitation of action and preemption issues in this case.

The Florida courts have on several occasions recognized the legal problems peculiar to victims of DES. In *Diamond v. E.R. Squibb & Sons, Inc.*, 397 So.2d 671 (Fla. 1981), this Court held that the products liability statute of repose could not constitutionally be applied to bar a DES claim which was not even discovered until after the statute's twelve year period. In *Conley v. Boyle Drug Company, supra*, this Court adopted a modified version of the market share theory of liability in recognition of the unique problems involved with DES caused injuries, even though it had previously refused to adopt that theory as to asbestos in *Celotex Corporation v. Copeland*, 471 So.2d 533 (Fla. 1985). Similarly, the instant case raises issues which are of acute

concern to the children of DES mothers.

II. THE DISTRICT COURT ERRED IN HOLDING THAT, AS A MATTER OF LAW, CARTER'S CLAIMS WERE BARRED BY THE STATUTE OF LIMITATIONS

In *Tanner v. Hartog*, 618 So.2d 177 (Fla. 1993), this Court receded from a line of prior decisions and held that, in medical malpractice cases, the knowledge of injury sufficient to trigger the running of the statute of limitations means not only knowledge of the injury, but also knowledge that there is a reasonable possibility (not a probability) that the injury was caused by medical malpractice (*i.e.*, knowledge not only of causation but also of a reasonable possibility of a departure from the standard of care). That continues to be the law. *Hillsborough Mental Health Center v. Harr*, 618 So.2d 187 (Fla. 1993); *Hanano v. Petrou*, 683 So.2d 637 (Fla. 1st DCA 1996). Whether a plaintiff knew of both the injury and the reasonable possibility that it was caused by medical malpractice is normally a fact question. *Copeland v. Armstrong Cork Company*, 447 So.2d 922 (Fla. 3d DCA 1984), *affirmed in part, quashed in part on other grounds*, 471 So.2d 533 (Fla. 1985).

The statute of limitations begins to run only when the moment of trauma and the moment of realization have both occurred; "trauma" means the damage or injury and "realization" means the "knew or should have known" element. *Steiner v. Ciba-Geigy Corporation*, 364 So.2d 47 (Fla. 3d DCA 1978), *cert. den.*, 373 So.2d 461 (Fla. 1979). Whether one, by the exercise of reasonable diligence, should have known that he or she had a cause of action against the defendant is ordinarily a question of fact for the jury. *Board of Trustees of Sante Fe Community College v. Caudill Rowlett Scott, Inc.*, 461 So.2d 239 (Fla. 1st DCA 1984), *rev. den.*, 472 So.2d 1180 and *rev. den.*, 472 So.2d 1182 (Fla. 1985).

Knowledge of injury alone, without knowledge it resulted from a negligent act,[2] does not trigger the running of the statute of limitations. *Elliot v. Barrow*, 526 So.2d 989 (Fla. 1st DCA 1988), *rev. den.*, 536 So.2d 244 (Fla. 1988); *Schafer v. Lehrer*, 476 So.2d 781 (Fla. 4th DCA 1985).

Knowledge of the negligent act sufficient to trigger the running of the statute of limitations means not just knowledge of the act itself, but also knowledge of the negligence. *Rogers v.*

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[2]Most cases in this area deal with negligence actions, but there seems to be no principled distinction between negligence and strict liability or implied warranty cases. For ease of reference, we will refer to negligence.

Ruiz, 594 So.2d 756 (Fla. 2d DCA 1991).

Knowledge of the mere possibility of negligence is not enough to trigger the running of the statute of limitations, absent knowledge of injury caused by the negligence. *Zukerman v. Ruden, Barnett, McCloskey, Smith, Schuster & Russell, P.A.*, 670 So.2d 1050 (Fla. 3d DCA 1996) (legal malpractice action based on negligence in connection with real property loan documents; statute of limitations would begin to run only when foreclosure action had been entirely resolved), *rev. den.*, 679 So.2d 774 (Fla. 1996); *Throneburg v. Boose, Casey, Ciklin, Lubitz, Martens, McBane & O'Connell, P.A.*, 659 So.2d 1134 (Fla. 4th DCA 1995) (legal malpractice action arising out of amendment to declarations of condominium action did not accrue when notice of claim of lien gave client notice amendment possibly was ineffective, but rather action accrued after court had so ruled), *dismissed*, 664 So.2d 248 (Fla. 1995); *Lane v. Peat, Marwick, Mitchell & Company*, 540 So.2d 922 (Fla. 3rd DCA 1989) (suit for accounting malpractice in connection with tax advice; action did not accrue when Internal Revenue Service issued deficiency letter, but only after court decision resolved issue), *approved*, 565 So.2d 1323 (Fla. 1990).

To trigger the running of the statute of limitations, plaintiff must have knowledge of the minimum facts essential to

give notice that a timely investigation should commence to discover additional facts needed to support a cause of action. *Harr v. Hillsborough County Mental Health Center,* 591 So.2d 1051 (Fla. 2d DCA 1991), *approved*, 618 So.2d 187 (Fla. 1993). In short, in this case, Carter had to have knowledge that he had cancer, not tuberculosis, before the statute would begin to run.

In the present case, Carter knew that there was something wrong with him on January 29, when he spit up blood. He acted with due diligence, consulting a home medical reference which indicated two potential causes -- tuberculosis and lung cancer. Tuberculosis was not a fanciful possibility, since Carter had been exposed to tuberculosis on the job. Carter promptly made a medical appointment, and on February 5 was told that an x-ray revealed a left upper lobe nodule which could be tuberculosis, could be a slowly resolving pneumonia, or could be cancer. His doctor deliberately down played the idea of cancer, and advised Carter that more tests were necessary to definitively diagnose his condition. In short, the doctor made a tentative diagnosis that Carter suffered from one of three conditions, only one of which, lung cancer, is associated with cigarette smoking. Only on February 14, when he was definitively diagnosed as having cancer, did Carter have knowledge that he indeed did have an injury

(cancer) which could have been caused by cigarette smoking and that an investigation should commence to discover additional facts needed to support a cause of action.

In similar situations, the courts of this state have on several occasions held that the statute of limitations does not begin to run when one has notice of an injury, but not of its cause. Thus, for instance, in *Board of Trustees of Santa Fe Community College v. Caudill Rowlett Scott, Inc., supra,* the plaintiff college had notice, more than four years prior to filing suit, that it was experiencing a substantial number of leaks in its underground piping system, but did not know, until less than four years before filing the complaint, what the cause of those leaks were. The First District held that the statute of limitations did not bar the action, and this Court denied two separate petitions for review of that decision.

Similarly, in *Almengor v. Dade County,* 359 So.2d 892 (Fla. 3d DCA 1978), a medical malpractice action, the plaintiff either was aware or should have been aware, more than the limitations period prior to filing suit, that their baby was born mentally retarded and thereafter showed signs of mental retardation and abnormal development. Because the evidence did not put plaintiff on notice as a matter of law that the baby was injured during birth (since

the baby could have been born with a congenital defect without any birth trauma), the court held that the statute of limitations did not bar the action.

Likewise in the present case, Grady Carter knew on January 29 that he had a medical problem and by February 5 that his condition might be one of three different things, two of which are not in any way related to cigarette smoking. It was not until February 14, when he was definitively diagnosed with cancer, that Carter knew that he had an injury which might be associated with cigarette smoking. Only then was he required to commence an investigation, and only then did the statute of limitations begin to run.

Where a plaintiff's injury is a creeping disease, such as asbestosis, the cause of action accrues when the facts giving rise to the cause of action are known or should have been known with the exercise of due diligence; this occurs when the accumulated effects of the substance manifest themselves to the claimant in a way which reasonably supplies some evidence of a causal relationship to the product. *Copeland v. Armstrong Cork Company, supra*. Although cancer cannot be categorized as a creeping disease, it is caused by the accumulated effects of exposure to cigarette smoke, just as asbestosis is caused by the accumulated effects of exposure to asbestos fibers. Accordingly, we suggest, this Court should hold

that the statute of limitations in a cigarette smoking case begins to run when the accumulated effects of cigarette smoking manifest themselves to the claimant in a way that reasonably supplies some evidence of a causal relationship between claimant's injury and the product.

Analytically, we suggest, a three-prong approach is necessary. First, the claimant must have knowledge that he has an injury. Secondly, he must have reason to believe that his injury is one which may be causally related to the product in question. Third, he must have some reason to at least suspect that tortious conduct by defendant was involved. (*i.e.*, that there had been medical negligence, or that the product was defective, or the like.)

The court in *Braune v. Abbott Laboratories*, 895 F.Supp. 530 (E.D.N.Y. 1995), applied such a test, stating (at 545):

> Independent of, and separate from, a plaintiff's awareness of the fact that she is medically impaired must be her awareness that her medical problem was "caused" by something extrinsic to her biology -- that someone has done something to her. A plaintiff may only discover aspects of her claim in pieces: (1) the fact that she has a medical problem; (2) that fact that the problem has a human cause; (3) the nature of the injurious agent (e.g., drug, gas, etc.); (4) the specific identity of the injurious agent (e.g., DES, asbestos); and (5) that fact that someone or some entity was liable, in some way, in

> connection with marketing, producing or distributing the causative agent.

In order for the statute to begin running, the court concluded, plaintiff must know that she has a medical problem and that the problem has a human cause.

Here, Carter knew on January 29 that he had a medical problem. However, he had reasonable grounds for believing that his condition might be one wholly unconnected to his cigarette smoking -- tuberculosis, to which he had been exposed in the workplace. He acted diligently and saw a doctor, who confirmed that tuberculosis was a possibility, as was cancer and a slowly resolving pneumonia. Thus, as of February 5, Carter did not know that he had an injury which might be causally related to the product (cigarettes); he only knew that he might have such an injury. To again quote the *Braune* court (at 551): "While paranoia is widespread, the law does not build upon it to demand that ill people assume that every medical problem they suffer resulted from the intervention of a malefactor."

As pointed out above, a mere possibility of causative negligence is not sufficient to trigger running the running of the statute of limitations. Only on February 14, when he learned that he did have cancer, not tuberculosis or pneumonia, did Carter have knowledge that his condition was one that might be caused by

cigarette smoking.

The statute of limitations does not begin to run where it is not possible to establish a causal relationship between the injury and the product. Thus, for instance, where medical science has not established a causal relationship between the product and the injury, the statute of limitations cannot begin to run. *Szabo v. Ashland Oil Company*, 448 So.2d 549 (Fla. 3d DCA 1984).

Likewise, the statute of limitations does not begin to run until a physician could establish <u>to a reasonable certainty</u> a cause-and-effect relationship between exposure to the product and a physical disability. *Brown v. Armstrong World Industries, Inc.*, 441 So.2d 1098 (Fla. 3d DCA 1983). In that case, plaintiff had begun experiencing shortness of breath in 1966 or 1967. He had heard of asbestosis in approximately 1970 or 1971, at which point he was retired. He became concerned at that point that his breathing problems might be due to exposure to asbestos, having read a newspaper article indicating that insulation workers were developing lung problems due to asbestos. It was not until 1979, however, that he was informed by any physician that he suffered from an asbestos related disease. The court observed (at 1099, emphasis supplied) that: "There is no showing by the defendants that any physician could have established <u>to a reasonable medical</u>

certainty - prior to 1979 - a cause and effect relationship between plaintiff's exposure to asbestos and his physical disability." Accordingly, the court reversed a summary judgment based on the statute of limitations defense. Similarly in the instant case, there was no showing that prior to February 14, 1991, any physician could have testified to a reasonable medical certainty that Carter had cancer rather than tuberculosis.

Respondent may argue, as it did in the district court, that the doctor's notes of February 5 established a causal relationship, and that knowledge of those medical records should be imputed to Mr. Carter. Factually, such a contention would be incorrect, since the medical notes list a number of impressions and do not purport to reflect any causal connection between a left lung nodule and cigarette smoking, any more than they reflect a causal connection between ulcers or kidney disease and cigarette smoking.

Moreover, we submit, imputation of knowledge of medical records is appropriate only when the claimant does not exercise due diligence to determine the facts which might have been revealed by those medical records. Thus, for instance, where a plaintiff's condition is not so severe as to put him or her on notice of a possible invasion of his or her legal rights through the exercise of reasonable diligence, knowledge of the contents of plaintiff's medical records will not be imputed. *Tetstone v. Adams*, 373 So.2d 362 (Fla. 1st DCA 1979), *cert. den.*, 383 So.2d 1189 (Fla. 1980).

Similarly, in *Higgs v. Florida Department of Corrections*, 654 So.2d 624 (Fla. 1st DCA 1995), an inmate brought a civil rights action against the Department of Corrections and prison physicians based on their failure to diagnose his injuries. On the day he was injured, the inmate went to the dentist, who took x-rays, but found

no indication of a fracture. The inmate later returned, declaring a medical emergency, and requested an x-ray of his face. He repeatedly went back to the prison clinic complaining of the same problem, and other x-rays were taken, but the doctors still did not spot the fracture in the x-rays. Finally, an x-ray report revealed a depression fracture and two other fractures; the inmate first learned of these x-ray results on August 9, 1990. The inmate contended that the statute of limitations began to run on that date, while defendants contended it began to run on March 21, when the inmate first began to believe the medical staff was improperly treating the injury. Citing a prior decision, the court held that a misdiagnosis constitutes evidence that plaintiff did not have knowledge that the injury was caused by negligence until the plaintiff received a correct diagnosis, and that a misdiagnosis would therefore, in most cases, raise an issue of material fact concerning plaintiff's knowledge, precluding summary judgment. Accordingly, the court reversed the summary judgment for the defense. Notably, in that case, the inmate acted with due diligence in trying to discover what the problem was. Even though the earlier x-rays in fact revealed the fracture, and had simply been misread, the court did not impute knowledge of those x-rays to the plaintiff, since he acted with due diligence.

Again, in *Nolen v. Sarasohn*, 379 So.2d 161 (Fla. 3d DCA 1980), an x-ray was taken on September 6, 1968, and the x-ray report in medical terms stated that there was nothing out of the ordinary. In fact, the report was incorrect, and the x-ray showed an abnormality which raised a suspicion of a tumor. Subsequently, another doctor examined the earlier x-ray and found the abnormality. The patient was told of the abnormality, but was not told that it had appeared on the 1968 x-ray. In December of 1975, he was told for the first time that he might have a cause of action for the 1968 misdiagnosis, and he filed suit in January of 1977. The trial court entered summary judgment for the defense based on the statute of limitations, and the district court reversed. The district court noted that there was no evidence to suggest that plaintiff possessed any medical knowledge beyond that of the ordinary lay person, and accordingly ruled that the contents of the reports need not as a matter of law be imputed to him. In short, the court said, if plaintiff could prove that he could not have discovered until December 1975 that his 1968 x-ray was misinterpreted, the cause of action would have been filed within the applicable statute of limitations. Accordingly, defense summary judgment was reversed.

In *Copeland v. Armstrong Cork Company, supra*, an asbestosis

case, the district court reversed a summary judgment for the defense based on the running of the statute of limitations. In that case, plaintiff first became aware of possible health hazards from asbestos in 1958 or 1959. Subsequently, he heard general rumors that asbestos dust could be harmful to one's health. In the late 60's, he began experiencing physical discomfort. In April, 1972, he experienced more serious symptoms and immediately consulted two doctors, both of whom diagnosed his condition as pneumonia and emphysema. Neither doctor linked the condition to plaintiff's work, although one did suggest a change in jobs to avoid dusty conditions at the job site. Plaintiff retired in April of 1975. In 1978, another doctor diagnosed plaintiff as having asbestosis, contracted as a result of long-term exposure to asbestos dust. Suit was filed in April of 1979. The trial court entered summary judgment on the ground that the action was time barred, but the district court reversed, finding that a factual issue was presented. The district court observed that, on the facts before it, a jury could reasonably conclude that plaintiff first acquired the relevant knowledge prior to April of 1975, but further observed that reasonable persons could likewise conclude that he did not acquire the relevant knowledge until the doctor diagnosed his condition as being asbestosis. Among the factors the

court found decisive was the plaintiff's consultation with two doctors immediately after serious symptoms appeared, when those doctors diagnosed his condition as being one which was unrelated to his job.

The instant case differs slightly from *Copeland*, in that there was not a misdiagnosis, but rather a tentative differential diagnosis of three possible conditions, only one of which is causally related to cigarettes. *Copeland* should not be read, however, as holding that a positive misdiagnosis is necessary to prevent plaintiff from acquiring the relevant knowledge. Rather, properly read, *Copeland* merely stands for the proposition that a misdiagnosis is evidence of a reasonable basis for plaintiff's belief that his condition might not result from the product. Here, Carter had a reasonable basis for thinking that his condition might be one unrelated to defendants' product. Both his home medical reference and his doctor told him that his condition might be the result of tuberculosis, to which Carter had been exposed on the job. Thus, he had a reasonable basis for believing that his condition might not be cancer. He acted with due diligence in determining what the condition was. His action was timely filed, since the reasonable possibility that he had tuberculosis was excluded on February 14, within the statutory period.

Moreover, the evidence reveals that the March 5 diagnosis, even if it had been one of cancer caused by cigarette smoking (as noted above, the diagnosis at that time was of possible tuberculosis, possible pneumonia, or possible cancer, and the medical notes did not establish any causal connection with cigarettes), it was a tentative diagnosis. The doctor himself testified that more testing was necessary to confirm whether Carter's condition was cancer.

A tentative diagnosis, however correct it turns out to be, does not start the clock on a medical malpractice case arising out of an earlier negligent failure to properly diagnose. *Ash v. Stella*, 457 So.2d 1377 (Fla. 1984). In that case, the diagnosis on which the trial court based its decision that the statute had run was a preliminary diagnosis, and tests to confirm it were not performed until six days later, with final results not being available until the following day. This Court stated (at 1379) "We do not believe that, as a matter of law, a tentative diagnosis, however proper it may turn out to be in hindsight, starts the clock on an action for medical malpractice arising out of negligent failure to properly diagnose."

Similarly, in *Colon v. Celotex Corporation*, 465 So.2d 1332 (Fla. 3d DCA 1985), *quashed on other grounds*, 523 So.2d 141 (Fla.

1988), the court observed that plaintiff may very well have been told by his doctor, more than the statutory period before filing suit, that he had asbestosis, but that the diagnosis was a preliminary one and did not necessarily start the running of the statute of limitations. The plaintiff's doctor in that case provided an affidavit pointing out that it was his customary practice not to make a final diagnosis of occupational disease until after a review of the test results and x-rays. The district court held that there was a material factual issue whether plaintiff, based solely on the tentative diagnosis, knew or should have known that he had a cause of action against the defendants more than the limitations period prior to filing suit.

Similarly, in the instant case, Carter on February 5 had only a tentative and preliminary diagnosis, not a definitive one. Moreover, the diagnosis given by his doctor also indicated that his condition might also be one of two things unrelated to cigarette smoking. Just as a tentative diagnosis which turns out in retrospect to be correct does not start the medical malpractice limitations clock, we submit, a tentative diagnosis, no matter how correct it turns out to be, should not start the products liability limitations clock.

Finally, we note that Brown & Williamson, in the First

District, also argued that the March 5 impressions also listed COPD. Brown & Williams argued that the diagnosis of COPD was, in and of itself, sufficient to start the statutory clock, regardless of whether there had been a diagnosis of cancer. We will not here repeat the points that were made above about the tentative nature of the diagnosis and the fact that imputation should not occur where claimant has acted with due diligence. We do, however, wish to make a further point. We submit that where exposure to a product can cause more than one unrelated disease in the same person at different times (or more than one adverse medical condition), even a definitive diagnosis of one such condition should not start the statutory clock on another condition which the plaintiff does not have reason to believe may also exist.

Both COPD and cancer can be caused by smoking cigarettes. They are otherwise unrelated (except insofar as both are lung problems). It is quite possible for a cigarette smoker to develop COPD, but never develop cancer, or to develop cancer but never COPD, or to develop both at different points in time. In such a situation, we submit, the applicable statute of limitations on a cause of action should run from the time plaintiff knew or should have known the requisite facts as to each medical condition viewed separately. That is to say, if Carter knew he had COPD on February

5, but did not know he had cancer until February 14, any claim for COPD would be time barred, but the claim for cancer would not be, since it was a separate disease, discovered at a different time.

This issue is significant to amicus, in that *in utero* exposure to DES can cause different adverse medical conditions in the same person at different times. Thus, for instance, consider the situation of a DES daughter who is told by her doctor that she was infertile, and that *in utero* exposure to DES might be a cause, but who did not learn until years later that she also had clear cell adenocarcinoma, again possibly due to *in utero* exposure to DES. If the woman had decided to become a nun, or to remain celibate, or even simply did not wish to have a family, she might not be inclined to institute costly and time-consuming litigation as to the infertility problem because she felt she had not been harmed significantly. But if the statute of limitations on <u>any</u> DES-caused injury triggered the running of the statute on <u>all</u> DES-caused injuries, that same woman would be forced to institute litigation which might not have otherwise been filed, and to seek recovery for the possibility that she might later develop carcinoma, or risk being without remedy if she indeed did develop adenocarcinoma at a later date.

A similar situation occurred in *Eagle-Picher Industries, Inc.*

v. Cox, 481 So.2d 517 (Fla. 3d DCA 1985), *rev. den.*, 492 So.2d 1331 (Fla. 1986). In that case, plaintiff had contracted asbestosis and, also as a result of exposure to asbestos, had an increased risk of later contracting cancer. He brought suit, and sought to recover damages for the increased risk of cancer. The district court pointed out that permitting a plaintiff to recover for the increased risk of contracting cancer in the future would be inequitable, reasoning that a jury would recognize that an increased risk of cancer did not necessarily mean that plaintiff would in fact contract cancer, and would accordingly reduce the damages awarded to reflect the possibility that plaintiff might never develop cancer. If, in fact, the plaintiff never did develop cancer, the court reasoned, the plaintiff would receive a windfall -- risk of cancer damages without having cancer. If, on the other hand, the plaintiff did develop cancer, he would not have received full compensation. The court resolved the problem by holding that plaintiff in such a situation would not be permitted to recover for the increased risk of cancer, but, should he later develop cancer, plaintiff would not be precluded from bringing suit for that separate injury.

We submit that the district court in *Eagle-Picher* reached the correct result, holding that two causes of action would be

permitted, accruing at different times, even though it did so while speaking in terms of splitting a single cause of action. In fact, we submit, such a plaintiff would not be splitting a single cause of action (permissibly or otherwise) but would instead be asserting two different causes of action -- one for asbestosis and one for cancer -- both caused by the same product at different times.

For the same reasons espoused in *Eagle Picher*, we submit, a DES daughter with infertility problems caused by *in utero* exposure would not be permitted to recover in that action for her increased risk of later developing clear cell adenocarcinoma. She would, however, under *Eagle Picher's* rationale, later be permitted to bring a separate action if she later developed that condition. That would not be splitting the cause of action, as the *Eagle Picher* court termed it, but rather simply reflects a recognition that two separate causes of action are involved.

Similarly, in the instant case, Mr. Carter would not be splitting a single cause of action if he had been diagnosed with COPD and later diagnosed with cancer. Rather, he would have two separate causes of action, accruing at separate times. The fact that his action for COPD might be time-barred should not, in and of itself, bar his action for cancer.

Courts in other jurisdictions have followed this two-injury rule in DES and other cases. Thus, for instance, in *Braune v. Abbott Laboratories, supra.*, a DES case, the court held that under New York's two-injury rule, diseases that share a common cause may nonetheless be held as separate and distinct injuries for limitation purposes where their biological manifestations are different, and where the presence of one is not necessarily a predicate for the development of the other. As that court summarized the rule (895 F.Supp. at 555-556):

> Where the statute of limitations has run on one exposure-related medical problem, a later exposure-related medical problem that is "separate and distinct" is still actionable under New York's two-injury rule. *Fusaro v. Porter-Hayden Co.*, 145 Misc.2d 911, 548 N.Y.2d 856 (Sup.Ct.N.Y.County 1989), *aff'd*, 170 A.D.2d 239, 565 N.Y.S.2d 357 (App.Div. 1st Dep't 1991). Under the rule, diseases that share a common cause may nonetheless be held separate and distinct where their biological manifestations are different and where the presence of one is not necessarily a predicate for the other's development. *See id.*, 548 N.Y.S.2d at 859.
>
> This "splitting" of what once might have been considered a single cause of action was a widespread development required by the growth of mass torts predicated upon latent injuries.

In *Green v. American Pharmaceutical Company*, 86 Wash. App. 63, 935 P.2d 652 (1997), another DES case, the court held that the discovery rule applied separately to injuries related to

plaintiff's hooded cervix and her later discovered t-shaped uterus, in view of uncontroverted expert testimony that the two conditions represented separate and distinct injuries. Accordingly, the court held, the discovery rule applied separately to each injury, and the statute of limitations did not begin to run until plaintiff knew or should have known that she had an injury that she could not have discovered earlier.

The two-injury rule has been applied in contexts other than DES. *See, for instance, Wilber v. Owens-Corning Fiberglass Corporation*, 476 N.W.2d 74 (Iowa 1991); *Sackman v. Liggett Group*, 167 F.R.D. 6 (E.D.N.Y. 1996); *Giffear v. Johns-Manville Corporation,* 632 A.2d 880 (Pa. Super. 1993); *Dempsey v. Pacor, Inc.*, 632 A.2d 919 (Pa. Super. 1993).

Likewise, we submit, this Court should adopt the two-injury rule and hold that, even if Carter's claims for COPD were time barred, his claim for cancer damages was not.

III. THE TRIAL COURT DID NOT ERR IN ADMITTING EVIDENCE RELEVANT TO ISSUES THAT WERE NOT PREEMPTED BY FEDERAL LAW

In this case, the trial court correctly ruled that any claim based on a failure to warn of the dangers of cigarette smoking after July 1, 1969 was preempted by federal law, and so instructed the jury. Carter had raised claims based on failure to warn prior

to that date, as well as claims based on other theories. Both before and during the trial, Brown & Williamson took the position that cigarette smoking had not been linked to cancer with sufficient medical certainty, and that cigarettes were not addictive. Carter responded that the evidence in question was relevant to the failure to warn claim prior to July 1, 1969, and to impeachment of Brown & Williamson's positions.

It is not the position of an amicus curiae to argue specific evidentiary issues and, although we agree with Carter's position in this case, we leave to Carter's counsel the specifics of the issue. We do, however, have an interest in the proper application of federal preemption law, and it is to that we now turn our attention.

Federal law may supersede state law, including state common law damage actions, in three situations: (1) where Congress has so stated in express terms; (2) where an intent to preempt can be inferred from a scheme of federal regulation which is so comprehensive as to leave no room for supplementary state regulation; and (3) where state law is in conflict with federal law because compliance with both is impermissible or because state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. *Cipollone v. Liggett*

Group, Inc., 505 U.S. 504, 112 S. Ct. 18, 120 L.Ed. 2d 407 (1992); *Vango Media, Inc. v. City of New York*, 34 F.3d 68 (2d Cir. 1994); *3M Health Care, Ltd. v. Grant*, 908 F.2d 918 (11th Cir. 1990). *See also, to like effect, U.S. Borax, Inc. v. Forster,* 24 F.L.W. D1220 (Fla. 4th DCA 1999). Congressional enactment of a provision defining the preemptive scope of a statute implies that it intended to limit the preemptive scope of the statute to the express terms of the preemption provision. *Cipollone v. Liggett Group, Inc., supra*; *Lohr v. Medtronic, Inc.*, 56 F.3d 1335 (11th Cir. 1995), *affirmed in part*, *reversed in part on other grounds*, 518 U.S. 470, 116 S. Ct. 2240, 135 L.Ed.2d 700 (1996); *Myrick v. Freuhauf Corporation*, 13 F.3d 1516 (11th Cir. 1994).

The party claiming preemption bears the burden of proof, and must establish that Congress has clearly and unmistakably manifested its intent to supersede state law. *Hernandez v. Coopervision, Inc.*, 691 So.2d 639 (Fla. 2d DCA 1997). Preemption of actions within the traditional police powers of a state should not be lightly inferred. *Medtronic, Inc. v. Lohr,* 518 U.S. 470, 116 S. Ct. 2240, 135 L.Ed.2d 700 (1996); *Lewis v. Brunswick Corporation*, 107 F.3d 1494 (11th Cir. 1997); *Myrick v. Freuhauf Corporation, supra*.

In light of the strong presumption against preemption,

preemption clauses must be narrowly construed. *Cipollone v. Liggett Group, Inc., supra*; *Lewis v. Brunswick Corporation, supra*. A federal statute which preempts a claim that labeling was inadequate does not preempt claims based on other theories. *ISK Biotech Corporation v. Douberly*, 640 So.2d 85 (Fla. 1st DCA 1994); *Brennan v. Dow Chemical Company*, 613 So.2d 131 (Fla. 4th DCA 1993). *See also, to like effect, Hernandez v. Coopervision, Inc., supra.*

As applied to the present case, two statutes are pertinent. The first is the 1965 Federal Cigarette Labeling and Advertising Act. That act required all cigarette packages in the United States to bear a conspicuous label stating: "CAUTION: CIGARETTE SMOKING MAY BE HAZARDOUS TO YOUR HEALTH." Section 5 of that act, captioned "preemption", provided in pertinent part:

> (a) No statement relating to smoking and health, other than the statement required by Section 4 of this Act, shall be required on any cigarette package.
>
> (b) No statement relating to smoking and health shall be required in the advertising of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.

The second pertinent statute is the Public Health Cigarette Smoking Act of 1969, which became effective July 1, 1969. That Act required a stronger warning on each cigarette package, as follows: "WARNING: THE SURGEON GENERAL HAS DETERMINED THAT CIGARETTE SMOKING IS DANGEROUS TO YOUR HEALTH." The 1969 Act also replaced

Section 5(b) of the 1965 Act with a new subsection 5(b) as follows:

> No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.

The scope of federal preemption under these two acts has been authoritatively resolved by the Supreme Court of the United States in *Cipollone v. Liggett Group, Inc.*, *supra*. In that case, the court held that the 1965 Act does not preempt state law claims for failure to warn, but that the 1969 Act does preempt any state law claim "with respect to the advertising or promotion" of cigarettes after its July 1, 1969 effective date. Neither the 1965 Act nor the 1969 Act bars state law claims unrelated to advertising or promotion. *Cipollone v. Liggett Group, Inc.*, *supra*; *Cantley v. Lorillard Tobacco Company, Inc.*, 681 So.2d 1057 (Ala. 1996); *Wolpin v. Philip Morris, Inc.*, 974 F. Supp. 1465 (S.D. Fla. 1997). Indeed, in *Wolpin v. Philip Morris, Inc.*, *supra*, the court held that the preemption provisions of the 1969 Act do not bar a claim by non-smokers who suffered from the results of second hand smoke.

In the present case, the trial court ruled, and so instructed the jury, that Carter was not presenting any claims based on a failure to warn after July 1, 1969. Rather, Carter's failure to warn claims were based on failures to warn between the time he

began smoking Lucky Strikes in 1947 and July 1, 1969. His claims based on smoking Lucky Strikes between July 1, 1969 and 1972, when he changed brands, were based on other theories. Thus, the trial court correctly followed *Cipollone's* mandate.

It must be emphasized that federal preemption is an issue preclusion doctrine, not an evidentiary doctrine. That is to say, where Congress has preempted the field, a party is barred from asserting liability on a state law claim based on the preempted issue. Thus, in the present case, Carter was barred from asserting any theory of liability based on inadequate warnings after July 1, 1969, as the trial court correctly ruled.

The fact that liability could not be imposed based on such a post-1969 failure to warn does not make evidence pertinent to such a warning inadmissible if it is relevant to some other valid issue. Thus, for instance, a document demonstrating that Brown & Williamson knew that cigarettes were addictive would properly be admissible to impeach its trial position that cigarettes were not addictive, even though liability could not be asserted under a theory that Brown & Williamson failed to warn, after 1969, of the addictive nature of cigarettes. It is the Evidence Code, not federal preemption law, which determines the admissibility of evidence. Federal preemption law only governs whether (in the

context of this case) Carter could recover under certain legal theories. It does not address, or even implicate, the admissibility of evidence.

CONCLUSION

This Court should hold that, under the circumstances of the present case, a jury question was present as to whether Carter's action was barred by the statute of limitations. Alternatively, the Court should adopt the two-injury rule, and hold that even if Carter's claim for COPD was time barred, his claim for cancer was not time barred. Finally, the Court should apply federal preemption law narrowly, and hold that the trial court correctly resolved the federal preemption issue, and that the Evidence Code, not federal preemption law, covers the admissibility of evidence.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a copy of the foregoing has been furnished to Robert P. Smith, Esquire, Hopping, Green, Sams & Smith, P.A., P.O. Box 6526, Tallahassee, FL 32314; J. W. Prichard, Jr., Esquire, Mosely, Warren, Prichard & Parrish, 501 West Bay Street, Jacksonville, FL 32202; Thomas E. Riley, Esquire, Chadbourne & Parke, LLP, 30 Rockefeller Plaza, New York, NY 10112; Gregory H. Maxwell, Esquire, Spohrer, Wilner, Maxwell, Maciejewski & Stanford, 444 West Duval Street, Jacksonville, FL 32202; Ada A. Hammond, Esquire, 200 W. Forsyth Street, Suite 1730, Jacksonville, FL 32202 this _____ day of June, 1999.

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JACK W. SHAW, JR., ESQUIRE