SUPREME COURT OF THE STATE OF NEW YORK
NEW YORK COUNTY

PRESENT: ALICE SCHLESINGER Justice

PART IA PART 16

Index Number : 112790/2010
CASABIANCA, ELIZABETH
vs.
MOUNT SINAI MEDICAL CENTER
SEQUENCE NUMBER : 001
DISMISS

INDEX NO. _____

MOTION DATE _____

MOTION SEQ. NO. _____

The following papers, numbered 1 to _____, were read on this motion to/for _____

Notice of Motion/Order to Show Cause — Affidavits — Exhibits _____ | No(s). _____

Answering Affidavits — Exhibits _____ | No(s). _____

Replying Affidavits _____ | No(s). _____

Upon the foregoing papers, it is ordered that this motion is by defendants to dismiss is denied in accordance with the accompanying memorandum decision.

FILED

DEC 03 2014

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MOTION/CASE IS RESPECTFULLY REFERRED TO JUSTICE FOR THE FOLLOWING REASON(S):

Dated: DEC 02 2014

Alice Schlesinger, J.S.C.
ALICE SCHLESINGER

1. CHECK ONE: ..... ☐ CASE DISPOSED ☒ NON-FINAL DISPOSITION

2. CHECK AS APPROPRIATE: .....MOTION IS: ☐ GRANTED ☒ DENIED ☐ GRANTED IN PART ☐ OTHER

3. CHECK IF APPROPRIATE: ..... ☐ SETTLE ORDER ☐ SUBMIT ORDER

☐ DO NOT POST ☐ FIDUCIARY APPOINTMENT ☐ REFERENCE

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

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ELIZABETH CASABIANCA, as Executrix of the Estate of ANGELO CASABIANCA, Deceased, and ELIZABETH CASABIANCA, Individually,

Plaintiff,

Index No. 112790/10
Motion Seq. No. 001

-against-

THE MOUNT SINAI MEDICAL CENTER, INC., KISHORE R. IYER, M.D. and GONZALO PATRICIO RODRIGUEZ-LAIZ, M.D.,

Defendants.

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SCHLESINGER, J.:

The Ebola epidemic that has commanded our attention today does not stand alone in relation to various other public health emergencies that this country has experienced. Probably the most recent one, as well as the subject of this action and motion, is the Swine Flu epidemic of 2009. Its more official name is the H1N1 influenza pandemic.

For this influenza a vaccine had been developed. But in the early stages of the crisis, the vaccine was in short supply. Responding to this shortage, various hospitals, including defendant The Mount Sinai Medical Center ("Hospital"), were instructed to establish emergency preparedness committees and follow guidelines as to which individuals would receive the vaccine. These guidelines were established by the Center for Disease Control ("CDC") and the New York State and City Departments of Health ("DOH"). While this problem of supply existed, vaccines were to be dispensed to children, pregnant women and hospital employees.

In this action, which sounds in medical malpractice and wrongful death, the decedent and subject of this action, Angelo Casabianca, did not receive this vaccine. Allegedly this was because he did not fit into one of the designated categories of eligible individuals. At least that seems to be a defense offered. Clearly, one of the claims his estate is making in the complaint, which was filed in 2010, is that the Hospital and doctors departed from accepted standards of care in failing to administer the vaccine to Angelo Casabianca.

Dr. Casabianca, a podiatrist, had gone to Mount Sinai to undergo a small bowel transplant, it was performed on September 17, 2009. Due to post-surgical complications, he remained in the hospital until November 5, 2009. Then he was discharged home. Paragraph 10 of the Complaint (attached to the Opposition as Exh A) reads in its entirety:

> That the defendants, the Mount Sinai Medical Center, Inc., Kishore R. Iyer, M.D. and Gonzalo Patricio Rodriguez-Laiz, M.D., its agents, servants and/or employees were careless, reckless and negligent in allowing and causing the plaintiff's decedent, ANGELO CASABIANCA, to contract the H1N1 virus, then commonly known as "swine flu"; the defendant failed to administer and/or make sure that the patient received the H1N1 immunization.

It is the plaintiff's contention that the decedent, being in a weakened condition from an intestinal transplant following the bowel resection, developed pneumonia, was exposed to the swine flu, and died on November 13, 2009.

The instant motion, based on a defense preserved in the defendants' Answer, asserts that this Court lacks subject matter jurisdiction and thus the action must be

dismissed. The argument is premised on an Act passed by Congress in 2005 known as The Public Readiness and Emergency Preparedness Act ("PREP") and codified at 42 USC §247d-6d. That law provides immunity from tort liability for manufacturers, distributors and administers of the vaccine during a public health emergency and further provides that the sole remedy resulting from injury would be under the Countermeasures Injury Compensation Program ("CICP).[1] Also, PREP preempts State law, which means that any action associated with injury from a vaccine must be brought in Federal Court. *See,* 42 USC §247d-6d(b)(8) .

The defendants here assert that the Hospital and the named doctors are covered under the PREP Act, meaning that this action, a tort action brought against them in State court, must be dismissed. However, the opposition argues that PREP is irrelevant to this action because, to be applicable, the vaccine must have been administered. It is undisputed here that the vaccine was never administered. That, according to the plaintiff as previously stated, was the problem.

Therefore, the issue before this Court is how to interpret PREP. Should it be given the broad interpretation urged by the defense so as to adopt the "statute's sweeping immunity" (Reply, p 4, ¶2), or rather should it be given the limited construct urged by the plaintiff?

Interestingly, few cases have been published dealing with PREP, and none actually addresses this issue. One decision cited by moving counsel, arguably in support of her position, is *Parker v Saint Lawrence County Public Health Dept,* 102

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[1]The act uses the word "countermeasure" as a substitute for vaccine.

AD3d 140 (3rd Dep't 2012). However, that opinion revolved around the issue of whether the PREP Act preempted plaintiff's state law claims for negligence and battery. The *Parker* action concerned plaintiff's daughter, a kindergarten student who, in December of 2009, had been inoculated with the H1N1 vaccine at a County clinic without parental consent.

The appellate court in *Parker* reversed the trial court and dismissed the complaint, broadly construing the preemption clause found within the Act. In arriving at this decision, the Third Department (at 144) found support in alternative relief included in the Act:

> Notably, Congress created an alternative administrative remedy — the Countermeasures Injury Compensation Program — for covered injuries stemming from countermeasures taken in response to the declaration of a public health emergency (see 42 USC §247d-6e(a); 74 Fed Reg at 51154), as well as a separate federal cause of action for wrongful death or serious physical injury caused by the willful misconduct of covered individuals or entities (see 42 USC §247d-6d[d]).

However, contrary to defense counsel's argument, this opinion does not aid in the decision making here because the little girl in *Parker* did receive the vaccine, while Dr. Casabianca in this case did not.

In Reply, moving counsel directs this Court to the words of the statute itself. That approach is the right one here, particularly since there is an absence of case law to aid in statutory interpretation. However, this Court disagrees with counsel's conclusions as to the application of the statute.

As earlier noted in this decision, "countermeasure" as used in the Act means vaccine. It is unclear why this substitution was made and the word countermeasure used in place of the word vaccine. Perhaps the word has a broader context, including other medical solutions in addition to vaccines. But what is clear is that whenever the topic of immunity from suit is discussed, qualifying words are always used. What are those words? They are "resulting from the administration to or the use by an individual of a covered countermeasure..."

An example is included in 42 USC §247-6d(a) entitled "Liability protections" and subdivision (1) entitled "In general." The entire clause (with emphasis added) reads as follows:

> Subject to the other provisions of this section, a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or ***resulting from the administration to or the use by an individual of a covered countermeasure*** if a declaration under subsection (b) of this section has been issued with respect to such countermeasure.

The referenced subsection (b) is entitled "Declaration by Secretary." It relates to the circumstances wherein the Secretary of Health and Human Services determines that a disease constitutes a public health emergency, thus triggering the implementation of the statutory protections of the Act.

Section 247d-6d(a)(3) says (with emphasis added) that:

> Subject to the other provisions of this section, immunity under paragraph (1) with respect to a covered countermeasure applies only if --

> (A) the countermeasure was ***administered or used*** during the effective period of the declaration that was issued under subsection (b)of this section with respect to the countermeasure;
>
> (B) the countermeasure was ***administered or used*** for the category of diseases, health conditions, or threats to health specified in the declaration; and
>
> (C) in addition, in the case of a covered person who is a program planner or qualified person with respect to the ***administration or use*** of the countermeasure, the countermeasure was ***administered to or used*** by an individual who [was in a population or geographic area specified in the declaration].

The Act excludes from its protections instances where willful misconduct was proved by the plaintiff (not this case). Subsection (c) sets forth the definition of willful misconduct, and paragraph (4) of that subsection, entitled "Defense for acts or omissions taken pursuant to Secretary's declaration," states that an individual "shall not have engaged in 'willful misconduct' as a matter of law where [the individual] acted consistent with applicable directions, guidelines or recommendations by the Secretary regarding the ***administration or use*** of a covered countermeasure..." (emphasis added).

In that same subsection, the Act states that one of the documents needed to prove that a patient suffered injury as a result of the vaccine is an affidavit from a non-treating physician. The physician must give reasons for his/her belief that the patient suffered serious physical injury or death "and that such injury or death was proximately caused by the ***administration or use*** of a covered countermeasure" (emphasis added).

In defendants' Reply, a 2012 Amendment to PREP is provided to the Court as Exhibit 1. Counsel quotes from two paragraphs, both under Section IX entitled "Administration of Covered Countermeasures." The first paragraph is quoted in its entirety, but in the second, certain parts are omitted. Both paragraphs are quoted below in their entirety with emphasis added, including part of a sentence not particularly relevant to the issues here.

> As clarified, the definition of "administration" extends only to ***physical provision of a countermeasure to a recipient***, such as vaccination or handing drugs to patients, ***and to activities related to management and operation of programs and locations for providing countermeasures to recipients,*** such as decisions and actions involving security and queuing, ***but only insofar as those activities directly relate to the countermeasure activities.*** Claims for which Covered Persons are provided immunity under the Act are losses caused by, arising out of, relating to, or resulting from ***the administration to or use by*** an individual of a Covered Countermeasure consistent with the terms of a declaration issued under the Act. Under the Secretary's definition, these ***liability claims are precluded if the claims allege an injury caused by physical provision of a countermeasure to a recipient, or if the claims are directly due to conditions of delivery, distribution, dispensing, or management and operation of countermeasure programs at distribution and dispensing sites.***
>
> Thus, it is the Secretary's interpretation that***, when a declaration is in effect, the Act precludes,*** for example, liability claims alleging negligence by a manufacturer in creating a vaccine, or ***negligence by a healthcare provider in prescribing the wrong dose,***

> ***absent willful conduct. Likewise, the Act precludes a liability claim relating to the management and operation of a countermeasure distribution program or site, such as a slip-and-fall injury or vehicle collision by a recipient receiving a countermeasure at a retail serving as an administration or dispensing location that alleges, for example, lax security or chaotic crowd control.*** [2] However, a liability claim alleging an injury occurring at the site that was not directly related to the countermeasure activities is not covered, such as a slip and fall with no direct connection to the countermeasure's ***administration or use***. In each case, whether immunity is applicable will depend on the particular facts and circumstances.

In this Court's opinion, the above-quoted provisions do not support the defendants' position that the Act applies here. This section continues to emphasize that the "administration" of the vaccine applies to the "physical provision of a countermeasure to a recipient". The language makes clear that the vaccine must be administered to or used by a patient. The amendment broadens the scope of persons covered by the Act, but it still only applies to the actual use of the vaccine in the manner in which it was intended; i.e., for "the administration to or use by an individual of a Covered Countermeasure consistent with the terms of a declaration issued under the Act".

Again, the injury must be one "caused by physical provision of a countermeasure to a recipient". In other words, something bad, perhaps not anticipated, has occurred from the administration or use of the vaccine, no matter what circumstances led to that

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[2] The portion that follows was omitted from the Reply papers.

use. Nothing is spoken of regarding a decision not to use the vaccine or of a failure to use it, whenever that decision was made or that failure may have occurred.

In the second paragraph quoted above, the language used clarifies that immunity is extended to slip and fall injuries and vehicle accidents that are connected to the vaccination process, be it at a retail store or some other facility. But a slip and fall or automobile accident not directly connected to the administration or use of the vaccine will not be exempt from liability.

The Act consistently speaks of administering or using the countermeasure. It appears to say, in the manner of common usage of words, that absent willful misconduct, when something bad happens to a person who has received a covered countermeasure (i.e., a vaccine), whichever individual is responsible for that bad result is immune from liability.

Further support for this interpretation is found in Section XIV of the above-reference 2012 Amendment, entitled "Countermeasures Injury Compensation Program". The first line of that clause reads in relevant part as follows:

> ... the PREP Act authorizes a Countermeasures Injury Compensation Program (CICP) to provide benefits to eligible individuals [or their beneficiaries] who sustain a serious physical covered injury or die as a direct result of the ***administration or use*** of a Covered Countermeasure.

Would any sensible person (including lawyers) seriously argue that someone like the plaintiff here, whose decedent never received the vaccine, could apply for such compensation? Certainly, Mrs. Casabianca could not avail herself of this relief. In the case of her husband, for whatever reasons, the vaccine (the covered countermeasure)

was not given. It was never administered to him or used by someone providing it to him. Thus, a claim for compensation pursuant to PREP could not be made.

However, a claim that could be made and in fact has been made here is that Dr. Casabianca's treating physicians, by deciding not to provide him with the vaccine, committed malpractice, which was a cause of his death. Such a cause of action is in no way covered by PREP, and the immunity from suit claimed by the defendants here simply does not exist.

Accordingly, it is hereby

ORDERED that defendants' motion to dismiss is in all respects denied.

Dated: December 2, 2014

DEC 0 2 2014

ALICE SCHLESINGER J.S.C.

FILED

DEC 03 2014

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