IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ZOLOFT (SERTRALINE HYDROCHLORIDE) PRODUCTS LIABILITY LITIGATION	:	MDL NO. 2342 12-MD-2342
	:	HON. CYNTHIA M. RUFE
THIS DOCUMENT RELATES TO ALL ACTIONS	:	

SPECIAL DISCOVERY MASTER'S REPORT AND RECOMMENDATION NO. 5 (REGARDING DISCOVERY BY DEFENDANTS OF EMPLOYMENT, SUBSTANCE ABUSE AND MEDICAL RECORDS)

October 22, 2013

I. INTRODUCTION

This multidistrict litigation is a consolidation of more than 400 cases in which plaintiffs allege that the ingestion of Zoloft, or Sertraline Hydrochloride, caused birth defects. There are 25 cases in an Initial Discovery Pool.

This Report and Recommendation No. 5 will address three disputed areas of discovery arising from requests for information by defendant Pfizer of the 25 plaintiffs whose cases have been selected for inclusion in the Initial Discovery Pool. In each of the 25 cases, Pfizer has made requests for access to records pertaining to the mental health of the mothers of the children allegedly affected by *in utero* exposure to Zoloft. Pfizer seeks records relating to the parents' substance abuse and substance abuse therapy. Pfizer also seeks the parents' employment records.

Pfizer seeks these materials either by disclosure of the records that the plaintiffs have or by having the plaintiffs and related individuals[1] execute authorizations allowing Pfizer to obtain the records. The two sides disagree on what the scope of this discovery should be.

II. MENTAL HEALTH HISTORY AND RECORDS

Pfizer's document request seeks "[a]ll documents . . . that relate in any way to . . . mental or physical health" of the affected minor or the mother from when the mother turned 18 to the present, or from twenty years ago to the present—whichever period is shorter. If the mother was 18 or younger when she gave birth to the affected child, Pfizer seeks records beginning three years before the mother gave birth. (Pfizer's request calls for all reports related to any health issue, but the controversy before me relates to mental health. There is no discussion about the father's mental health records in the motions presented.)

Plaintiffs' Steering Committee ("PSC") urges that the production of mental health records should not include records dating from the last time the mother gave birth to the present. The length of the time period for discovery before the mother's last pregnancy, therefore, is not at issue. The question is whether Pfizer should be able to discover records about the mother's mental health relating to the time period from the mother's most recent pregnancy to the present.

I conclude that Pfizer should be able to take that discovery, for the reasons that follow.

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[1] The injuries alleged are primarily to the minors who were *in utero* while their mothers ingested Zoloft. Other injuries or damages are alleged to have been sustained by parents. In cases where there are alleged to be injuries to minors, the plaintiffs are often guardians or parents. Rather than refer to plaintiffs, who might not be injured at all, this Report and Recommendation will refer to the allegedly injured minors, the mothers and the fathers, regardless of who the plaintiff is in any particular case.

A. Recent mental health records are reasonably likely to yield information related to the issue of liability.

First, mental health records generated since the pregnancy at issue are reasonably likely to be relevant to the issue of liability.

A key question relating to the liability of Pfizer will be whether any of the mothers' physicians would have declined to prescribe Zoloft to the mother if a different warning about risks of taking Zoloft during pregnancy or in childbearing years had been given by Pfizer. PSC argues that this question focuses on the doctor and what the doctor knew about the patient at the time the prescription was written. If this is the focus, PSC urges, there is no reason to know about the patient's mental health as it developed after the prescription was written.

There might be a case where one of the mother's physicians will testify, "If the warning urged by plaintiffs had been given, I would not have prescribed Zoloft to anyone." In that case, inquiries about the mother's psychological or psychiatric condition are not likely to be complicated at all. In that unusual instance, there may not be a reason to seek evidence of the mother's psychological or psychiatric condition during the period after the prescription was written.

However, the question of whether a doctor would have prescribed Zoloft in the face of a different warning is not likely to be so simple. What the mother has said about her psychiatric history in recent years might shed light on what her condition was during the pregnancy that is at issue in this case. This is not because her post-pregnancy condition is relevant to the decision about whether to prescribe before or during the pregnancy; it is because the contents of post-pregnancy records may shed light on what the condition of the mother was when the prescription at issue was written.

A doctor's evaluation of a patient's psychiatric condition and needs can be lengthy and nuanced, and its recordation in medical notes is not likely to be perfect or complete. Psychotherapeutic notes are often quite sparse, and it is common for repeated psychotherapeutic sessions to generate no notes at all, or the very simplest of notes that reflect merely that there was a patient consultation and a prescription written. At the other extreme, some physicians' files contain documentations of warnings that are quite lengthy, and they more comprehensive than what might realistically be expected to be given in the time frame of a normal consultation.

If the notes of the prescribing physician in one of the 25 cases are like that, then a subsequent visit to a new practitioner that generates a more complete or reliable medical history is likely to yield useful information. An effort to piece together a mother's mental health history is almost as likely to be informed and enhanced by medical notes generated after her last pregnancy as by medical notes generated during or before that pregnancy. Lengthy notes about psychiatric history and conditions may appear only sporadically in medical records, and if there is a complete history taken after the most recent pregnancy, it could well be quite descriptive of a mother's condition as it existed some time before. Indeed, it could be more descriptive of a mother's condition than any notes taken at the time of the prescription at issue. Recent notes that are more complete than the prescribing physician's own notes might help the doctor and the mother recall what the mother disclosed to the doctor about her medical history.

In a perfect world of comprehensive, consistent medical notes and perfect memories, the records from the period after the prescription at issue would not be useful. They would be cumulative or irrelevant. But where notes made after the prescription was written might be more comprehensive, reliable or informative than the notes taken at around the time of the

prescription, and where the notes might discuss the patient's history, it is worthwhile to look at the more recent notes.

PSC argues that in most states the focus of how the decision to prescribe was made turns almost entirely on the views of the physician who is the learned intermediary. It has been stated under New Jersey law, for example, that "the crucial question is whether the warning was adequate to apprise a physician, not a consumer, of the risks." Grobelny v. Baxter Healthcare Corp., 341 Fed. Appx. 803, 806 (3d Cir. 2009). Even if that is the crucial question in some states, however, it is not the only question. Under Pennsylvania law, for example, in Demmler v. SmithKline Beecham Corp., 671 A.2d 1151 (Pa. Super. 1996), the court stated, "the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative." Id., at 1154.[2] Even if the focus of who made the decision to prescribe and how is on the physician under cases such as this, the physician's focus must be, in turn, on what he or she knew about the patient. What the patient said when the prescription was written will doubtless be imperfectly recollected, and what the patient said to another physician later might assist the parties in development of their recollections.[3]

There is no doubt that memories of the mother's condition as of the time of the prescriptions at issue could be faulty. It might be that both the prescribing physician and the

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[2] On this point, the court was following the Restatement (Second) of Torts. 671 A.2d at 1155.

[3] The patient also makes an independent decision about whether to take a prescribed drug after the prescription is filled. Some patients take a drug simply because the doctor prescribed it; others override their prescriptions and are noncompliant. The mother's evaluation of how she reacted and what she did after the prescription was written will appear in more recent medical notes.

mother will have poor memories of what the mother's condition was. We know this from the history of this very litigation. PSC informed the Court that a substantial number of cases in this MDL were withdrawn after they were filed—including cases selected for the Initial Discovery Pool—because the plaintiffs and their counsel recognized that the mother had a faulty memory about whether she even took Zoloft at the relevant time. In those cases, the mother alleged Zoloft ingestion during pregnancy; no records could substantiate it, or records uncovered after the case was filed contradicted the allegations. (See Report and Recommendation No. 3, issued in this case August 23, 2013, at page 4, Dkt. No. 539) In at least one of the 25 Initial Discovery Pool cases, the plaintiff's fact sheet states that the mother does not recall when she took Zoloft.

Where memories are so likely to be imperfect and records of what was said between the mother and the physician may be incomplete, a full review of recent records is likely to be informative on the question of liability.

B. **Recent mental health records are reasonably likely to lead to admissible evidence on damages.**

The records of the mother's mental health conditions are likely to be relevant to her own damages. Nineteen of the Complaints filed by the Initial Discovery Pool plaintiffs make allegations about the emotional distress suffered by the mothers after their children were born with birth defects. A mother plaintiff's current mental health is relevant to the claims where she has alleged that she has incurred emotional distress. See, e.g., Vasconcellos v. Cybex Intern., Inc., 962 F.Supp. 701, 708-09 (D.Md. 1997) (holding that discovery of psychotherapy records is permissible but limited to information directly relevant to the lawsuit).

PSC stated in one of its submissions: "To be clear, there are no claims—none—made for the emotional distress of the Mother Plaintiffs." (PSC submission of September 26, 2013, page 3) Despite this, nineteen of the Complaints filed by the plaintiffs in the Initial Discovery Pool

cases refer to the emotional distress of the mother. While the PSC submission might be taken on its face to be incorrect, I understand the PSC to be saying that these 19 plaintiffs wish to decide later whether they will actually be pursuing damages based on the allegations of emotional distress that are set out in the Complaints.

In an MDL with the tight deadlines that the PSC has urged, we cannot postpone discovery about emotional distress until an undefined time when the plaintiffs decide whether or not to pursue claims for emotional distress. The discovery should be taken now because it will be too late to complete that discovery if we postpone it.

PSC's wish to have plaintiffs decide later about whether to allow discovery about emotional distress allegations that are in the pleadings is inconsistent with the purposes of having an Initial Discovery Pool in an MDL. Discovery about an issue like emotional distress in the representative cases informs the parties about the settlement value of other cases in the MDL. If PSC is permitted now, unilaterally, to decide that emotional distress is not an issue in the Initial Discovery Pool cases, then those cases are decidedly not representative of all of the other cases in the MDL where emotional distress has been alleged and will, presumably, be considered in settlement discussions. [4]

The mother's psychiatric condition is also likely to be relevant to the question of the damages of the child. PSC acknowledges, as one would expect, that each child has suffered emotional distress as a result of the birth defects at issue. A child will undoubtedly suffer stigma and psychological harm from a birth defect. A mother's statements about how the child is adapting to the defect may appear in the mental health records of the mother. In addition, a

[4] If, in the minority of Initial Discovery Pool cases, the mother's emotional distress is not at issue for damages purposes, the records are still likely to shed light on the question of liability, as discussed above, and on the child's emotional distress.

child's psychological and psychiatric development is reasonably likely to be affected by the mental health of the child's parents. The mother's contemporary mental health records will bear on the child's damages.

C. **Other considerations relating to discovery of mental health information**

After the briefing deadline, PSC submitted discussions of the law in a few states; PSC argues that in these states the privilege for medical records about mental health overrides the considerations of relevance. Some states have held, as PSC's discussion would have it, that mere allegations of "garden variety" emotional distress either do not constitute a waiver of the privilege or do not really place the plaintiff's mental health in issue. Regardless of what state law holds on the subject, we are in federal court; the extent to which the law cited by PSC is state procedural law about the scope of discovery, it does not dictate a decision made under Fed. R. Civ. P. 26. In Vasconcellos, supra, the court treated the psychotherapist-patient privilege as one of federal law, following Jaffe v. Redmond, 519 U.S. 1 (1996).

PSC's submissions about this aspect of state law are incomplete, and Pfizer's countersubmissions were neither required nor complete, primarily because the deadline for submissions had passed. If I were required to engage in a state-by-state study of this legal issue, it might consume a large part of the period during which discovery is to be taken. The parties had agreed that state by state law would not be considered in connection with the current submissions. The question before me turns primarily on the discovery requested falls within the scope of Fed. R. Civ. P. 26 and whether the temporal scope of the information sought should be limited in light of the needs of the MDL. I find that the discovery about mental health records does fall within the scope of Fed. R. Civ. P. 26 and that the temporal scope should not be

restricted in a way that precludes discovery of the records generated between the mother's last pregnancy and the present. I so recommend.

III. SUBSTANCE ABUSE INFORMATON

Pfizer requests all records relating to both the mother's and the father's history of substance abuse,[5] and of any treatment sought, received or considered. Pfizer places no temporal limits on the request; presumably it relates to the entire lifetime of either parent. Pfizer also requests records of any substance abuse that anyone has "sought or recommended" on the mother's behalf. (*See* Pfizer's September 6, 2013 Letter, at p. 7). PSC seeks to limit the production of the mother's substance abuse records from the period beginning nine months before the pregnancy at issue and ending nine months after that pregnancy; PSC seeks to limit the biological father's substance abuse treatment records to those in existence before conception. (*See* PSC's September 26, 2013 Letter, at pp. 5-6). PSC advanced compromise proposals that would call for discovery of the mother's substance abuse treatment records during the period of five years before the pregnancy at issue. (PSC letter of September 23, 2013, at p. 4)

The parties have not stated how many of the parents in these 25 cases have had substance abuse treatment.

The disagreement about discovery of substance abuse is not only about time frames. Pfizer seeks discovery about substance abuse therapy that has been sought or recommended for the mother, even if that therapy has not been given.

[5] The parties have not stated how they define "substance" within the meaning of the requests for information about substance abuse. I take it to refer to alcohol and non-prescription drugs. Perhaps it refers, as well, to misuse of prescription drugs, such as opioids. I do not know if any party considers abuse of prescribed drugs such as opioids to be relevant to any claim or defense, but records of prescription of these drugs are, in any event, likely to appear in medical records as to which there is no controversy at this time.

Pfizer seeks information related to the mother's substance abuse for the purposes of determining: (1) her willingness to take risks during pregnancy; (2) whether the fetus was exposed to harmful substances; and (3) whether post-birth exposure to toxins may be an alternate cause of the injuries alleged or a factor that aggravated the injuries.

Not all of Pfizer's arguments are persuasive. Pfizer's argument that a mother's substance abuse history reflects a willingness to take risks during pregnancy is not convincing. Some risks are bigger than others. There seems to be little logical connection between abuse of alcohol or illicit drugs and the choice of antidepressants that may be made after consultation with a physician.

Also unpersuasive are Pfizer's broad assertions about how substance abuse over the long term might be an alternative cause of the birth defects at issue. These assertions have not been supported by any scientific literature submitted in connection with the present motion. Perhaps literature like this will be presented later and be the subject of Daubert hearings, but none is before me now. I do not see any scientific basis for any assertion that abuse of alcohol or non-prescription drugs by either parent, if discontinued before the pregnancy at issue, could have caused the birth defects at issue.

Similarly, Pfizer has not provided in connection with this motion any medical or scientific literature demonstrating that abuse of alcohol or non-prescription drugs by a father causes any of the birth defects at issue. If such abuse by a father might cause such injuries, I cannot take judicial notice—or "Special Master notice"—of it. I do not, therefore, find the father's substance abuse relevant to the medical issue of what caused the birth defect. Similarly, if the father has been taking cocaine or abusing alcohol since the birth of the child, I am not aware of how that can have a direct impact on the physical condition of the child. Pfizer has not

documented how a mother's abuse of substances in the months after the birth would have had an impact on the particular physical conditions complained of in these cases.

Nevertheless, it is reasonable to relate substance abuse history to emotional distress damages sustained both by the mother and the child, both of which are alleged in the majority of the cases, as discussed above. Substance abuse by a parent could reasonably be expected to detract from the emotional wellbeing of that parent's child, as well as to the emotional wellbeing of the other parent. Therefore, substance abuse to the present by a mother or a father is likely to bear on the question of the child's damages for the emotional distress that is attendant to living with the consequences of the birth defects at issue. This leaves questions, then, about the temporal scope of discovery on this issue and about whether Pfizer may take discovery about substance abuse therapy that has been recommended, even if it has not been received by the parent to whom it was recommended.

The records of substance abuse therapy may or may not be more complete than those relating to mental health and mental health treatment. If they are as incomplete as those of mental health treatment, as discussed above in Section II, then discovery about them over a long time period is appropriate. Since it is reasonable to anticipate that they may be incomplete, it is reasonable and fair to require discovery over a long period in anticipation of that.

In addition, I am able to take notice of the nature of substance abuse as a disease that is difficult to treat. It is difficult to get a person who is abusing alcohol or non-prescription drugs to acknowledge the abuse, much less to get treatment. An abuser of alcohol or non-prescription drugs may go in and out of an active disease state many times over many years. A limitation on records about substance abuse that cuts off discovery of them only nine months before and after the pregnancy at issue is, in light of this, not reasonable. If we limit discovery to that time frame,

discovery is quite likely to miss information about substance abuse that actually occurred. It would probably prevent the disclosure of information that is reasonably likely to lead to the discovery of admissible evidence.

PSC has stated that there is statutory law that prevents the disclosure of substance abuse treatment records in the absence of good cause.[6] One of the statutes is 42 U.S.C. § 290dd-2. That statute only applies to treatments "conducted, regulated, or . . . assisted by any department or agency of the United States." 42 U.S.C. § 290-d(a). It is not clear that any substance abuse treatment that might be at issue on this motion was carried out with federal assistance. Also, there are exceptions for good cause, 42 U.S.C. § 290dd-2(b)(2)(C); good cause may be held to include the need to evaluate of a claim in a civil action that is based on the psychological condition of the person who was treated. Mulholland v. Dietz Co., 896 F.Supp. 179 (E.D. Pa. 1994); O'Boyle v. Jensen, 150 F.R.D. 519, 521-22 (M.D. Pa. 1993). Based on what has been presented on this motion, federal statutory law does not prevent the discovery requested.

Federal law aside, the briefing demonstrates that there may be a wide split in state law on the issue of non-disclosure of substance abuse treatment records. There is a common thread to what has been presented in the briefs which comports with the discovery standard of relevance under Rule 26 and permits a court to balance privacy against the need for disclosure.[7] As is the

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[6] The federal statute at issue does not protect the recipient of substance abuse treatment from having to disclose the fact that he or she was treated; it appears merely to protect the recipient from disclosure of records generated by the treatment.

[7] One commentator notes that many courts have deferred to federal privilege rules because it is difficult to "incorporate the varied provisions of different states' privileges." Anne Bowen Poulin, THE PSYCHOTHERAPIST-PATIENT PRIVILEGE AFTER JAFFE V. REDMOND: WHERE DO WE GO FROM HERE?, 76 WASH. U. L. Q. 1341, 1346-1347 (1998); *see also Wm. T. Thompson, Co. v. General Nutrition Corp.*, 671 F.2d 100, 104 (3d Cir. 1982) (holding that federal law favoring admissibility rather than state law privilege governed); *Johnson v. Nyack Hosp.*, 169 F.R.D. 550, 558 (S.D.N.Y. 1996) (rejecting argument that state peer review privilege applied and stating that "the goal of the exercise is the informed determination of a single, uniform federal law of

case when the federal statute limiting disclosure is applied, the assertion of damages claims relating to the emotional conditions of the mothers and the children has put the mental health of those individuals in issue, and there is good cause for overriding the limits on disclosure. The time frame should be as broad, for the reasons discussed above.

The discovery of substance abuse treatment is primarily for the purposes of determining issues related to emotional distress of the parents and the children. At least on the record presented, it does not appear likely to be useful for determining issues of how the birth defects alleged were caused. Disclosure of of records of a parent's substance abuse treatments during the period beginning ten years before the pregnancy at issue to the present is reasonably likely to lead to discovery of admissible evidence on the point of emotional damages.

This leaves the question of whether the plaintiffs should be required to disclose documents reflecting that someone has "recommended" substance abuse treatment to one of the parents, and documents about whether the parent has sought such treatment. Documents of this nature that are in medical records and mental health records are likely to be lead to admissible evidence or to be probative of substance abuse. Documents that are outside of such records would not likely be from authoritative sources who are trained to recognize substance abuse. A note from a neighbor, a friend or a supervisor at work urging substance abuse treatment should not be discoverable; a medical note stating that the physician urged such treatment should be discoverable.

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evidentiary privileges"). Although this commentator was discussing privileges under federal common law, the need for uniformity is a consideration here where mothers are from a variety of different states. The considerations are similar to those relating to the privilege for communications to psychotherapists. See page 8, above.

IV. EMPLOYMENT RECORDS

Finally, Pfizer requests all of both parent's employment records over the last twenty (20) years. (*See* Pfizer's September 23, 2013 Letter, at p. 5). Pfizer argues that such records would not only help evaluate lost wage claims, but that they would also reveal the mother's occupational exposure to harmful substances. *Id.* Pfizer also justifies its request by asserting that employment records contain information on the mother's mental health, and that such records are in issue due to allegations of physical and emotional injuries. (*See* Pfizer's September 26, 2013 Letter, at p. 6).

In recognition of the lost wages claim, PSC has agreed to produce employment records for the ten years prior to birth of the children, through the period of the alleged loss and only where lost wages are claimed. (*See* PSC's September 23, 2013 Letter, at p. 6). PSC urges that any record of exposure to toxic substances would be revealed in the mother's pharmacy and medical records and that a "neatly tailored interrogatory requesting information related to any potential exposures" will suffice to identify periods of occupational exposure to harmful chemicals. *Id.*

First, Pfizer's argument that employment records will reveal information related to mother's mental health is unavailing. Pfizer argues that there might be evidence of behavior indicative of poor mental health, or a record of absences that reflects depression. First, the mothers acknowledge that they were depressed at various times; this is inherent in a lawsuit that arises from the ingestion of an antidepressant. Second, the examination of employment records to determine the mental health of the employee is no more likely to yield meaningful psychiatric information than is examination of almost anything else. The records are not likely to contain

professional evaluations, and the collection of them is not reasonably calculated to yield information about the mental health of an employee.

The information in employment records might yield information about exposure to toxic substances. But, as is stated above, the relationship between exposure to toxic substances in the past, when that exposure has been discontinued, and birth defects arising from a more recent pregnancy has not been documented for purposes of this motion. In addition, the exposure to toxic substances is readily inquired into in a focused way after the defendant examines the employment history that the mother has given. If a mother reveals that she has worked in factories and facilities where toxic substances are likely to be used, then discovery of the records from that facility's company might be appropriate; if the mother has worked in a series of stores and offices, then discovery of employment records for purposes of learning more about exposure to teratogenic substances would not be justified.

Obtaining records going back as far as twenty years about 25 pairs of parents for purposes of learning about their exposure to teratogenic substances is not justified. There is no need to obtain 1,000 years of employment records for that purpose when interrogatories and more targeted discovery after they are answered will accomplish this purpose.

Second, Pfizer seeks an entire employment history on the basis of Mother Plaintiffs' lost wage clams. Although Mother Plaintiffs do actually put their employment history "in issue" by asserting lost wage claims, Pfizer's request is more broad than is justified. See, e.g., Crowe v. Booker Transp. Servs., 2013 U.S. Dist. LEXIS 13376, at *11 (W.D. Mo. 2013) (citing *State ex rel. Delmar Gardens North Operating LLC v. Gaertner*, 239 S.W.3d 608, 611-612 (Mo. 2007)) ("Where the information requested in the personnel file is sufficiently related to the issues in the pleadings, it is discoverable. A request for an entire personnel file, however, is overbroad.").

For this reason, I rely upon the approach in Seale v. Smithkline Beecham Corp, C.A. No. 07-cv-180, Order (N.D. Miss. Sept. 22, 2008), and find that discovery relating to a reasonable period preceding the alleged loss through the period of the loss is reasonable. PSC has suggested a period of ten years prior to the alleged loss through the alleged loss, and this should be adequate.

V. CONCLUSION

I recommend that discovery of the mothers' mental health records, where emotional distress of any person is alleged, should be allowed for the entire period of the adult life of the mother, or for the past twenty years, whichever is shorter. In cases where the pregnancy at issue was completed when the mother was 18 or younger, the records for the three years preceding the birth through the present should be made available.

I recommend that substance abuse treatment records of either parent dating from ten years before the pregnancy at issue to the present be made available during discovery. Records of professional recommendations that the mother receive substance abuse treatment during that period should also be made available.

I recommend that employment records of any person who is alleged in the pleadings to be seeking damages for lost wages be made available where those records relate to employment during the ten years preceding the pregnancy at issue through the end of the period of the wage loss claim. Each parent, regardless of whether lost wages are sought, is required to provide a comprehensive lifetime employment history.

10/22/13

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