IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS

IN RE: CLAIMS FOR VACCINE INJURIES RESULTING IN AUTISM SPECTRUM DISORDER, OR A SIMILAR NEURODEVELOPMENTAL DISORDER,	*	Autism Master File
Various Petitioner(s),	*	**NON-PARTY MERCK & CO.'S REPLY TO PETITIONER'S RESPONSE RE NON-PARTY DISCOVERY**
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

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Merck & Co., Inc. ("Merck") submits this Reply Memorandum in answer to Petitioners' Response to Merck and Amicus Curiae re Non-party Discovery ("Petitioners' Response").

INTRODUCTION

Because the Vaccine Act permits third-party discovery only when it is necessary to the Special Master, Petitioners' request for a subpoena must be denied. That conclusion is now made even more evident by Petitioners' failure to articulate why the Special Master would be unable to make a proper finding on causation notwithstanding (a) the abundant, on-point, peer-reviewed published literature, including especially that which appeared in print during the past two years (cited by Merck and ignored by Petitioners) and (b) whatever work Petitioners' experts have done. Implicit in the statutory threshold of "necessity" -- different from mere relevance -- is the obligation of the party seeking discovery to identify the available information and show why it will not

do. Petitioners appear to acknowledge this requirement, but their attempt to satisfy it falls far short.

Given that the Vaccine Act's necessity standard is the governing law, the matter should end there. It also bears mention, however, that denial of the subpoena also fairly accommodates the two policy considerations implicated by the subpoena request:

- On the one hand, denial of the subpoena request would not undermine the Special Master's ability to adjudicate fairly and accurately the causation issue before him. In the past year alone, medical journals of great stature such as the Journal of the American Medical Association and Pediatrics have published multiple studies about the purported relationship between autism and thimerosal. The existence of this literature, in combination with other previously published literature, assures that the Special Master can provide Petitioners a resolution of their causation claims that is based on careful, focused, independent peer-reviewed medical studies. He also will have a chance to hear from Petitioners' experts who presumably are ready to argue a view contrary to the published literature.[1]

- On the other hand, denial of the subpoena request would further the sound Congressional public heath objective of attempting to assure the continued supply of childhood vaccines -- products that save real lives of countless real children -- by sparing manufacturers from the expense of the litigation process. As shown infra, and as common sense would dictate, this desire was expressed by Congress both in terms of liability exposure and litigation expense, the accounting classification of the drain on corporate resources being of no consequence to the Congressional purpose.

In short, given the substantial literature available to the Special Master, the perhaps strategic decision made by the Petitioners to conceal the progress of their experts' efforts

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[1] Though not surprising, Petitioners' decision not to submit affidavits from their experts regarding alleged "gaps" in the scientific record is an act of gamesmanship for which there ought to be consequences. An affidavit bearing today's date from an expert in Petitioners' stable admitting that after two years of research and analysis he or she still cannot find causation obviously would be very damaging to Petitioners down the road. Yet Petitioners stand before the Special Master and ask him to find that he needs to burden the vaccine manufacturers with broad discovery because Petitioners cannot prove causation, while Petitioners' experts remain safely hidden from view. At the barest minimum, Petitioners should have presented affidavits to explain why the Special Master should find that there are gaps preventing him from ruling on causation,

to develop a theory of causation, and the sensible and binding public heath policy that prompted Congress to establish a compensation scheme in which injured vaccine recipients can receive awards, but from which the suppliers of life-saving vaccines are insulated, Petitioners' request for a subpoena should be denied.

Merck responds as follows to specific points raised in Petitioners' Response.

I. The Subpoena Sought By Petitioners Should Not Issue.

As Petitioners concede, they have no right to third party discovery unless that discovery is necessary to the Special Master's determination of whether thimerosal in vaccines causes autism-spectrum disorders. Although Petitioners mischaracterize some of Merck's arguments, and ignore others completely, they still cannot show that the Vaccine Act allows issuance of the requested subpoena under the circumstances here.

A. Petitioners have not shown that discovery from the vaccine manufacturers is "necessary."

Petitioners' arguments boil down to just one point: Years after they began filing claims, they and their experts still have failed to find or develop evidence to show that thimerosal in vaccines causes autism. By Petitioners' twisted logic, it is precisely because they have filed claims that they still cannot support that the Special Master should burden other parties to facilitate Petitioners' desire to keep digging for more. Surely, that cannot be what Congress intended when it effectively issued a mandate against full-throttle discovery by providing that it would be allowed only when it was "necessary" to the Special Master's determination.

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notwithstanding Petitioners' experts' opportunity to conduct years of analysis and the abundant recent scientific literature.

The Special Master should consider the unspecific nature of what Petitioners have put before him. For example, Parts B.1 through B.4. of the requested subpoena seek documents that could relate to any conceivable theory of causation, even if it does not involve autism or any other neurological condition (see Requested Subpoena §§ B.1, 2.), even if it does not involve thimerosal (see Requested Subpoena § B.3.), and even if it involves neither a neurological condition nor thimerosal (see Requested Subpoena § B.4.). Petitioners incorrectly state that their request for documents "is limited to a specific product, for a specific period of time, and seeks specific information about the link between one product and one type of injury." (Petitioners' Response at 7.) That statement simply cannot be reconciled with the terms of the subpoena.

Similarly, Petitioners make no effort to link the subpoena's document categories to any particular unanswered question in the scientific literature. Petitioners also do not disclose where any such unanswered question fits within the theory of causation that they anticipate asking the Special Master to accept. By seeking documents pertaining to all possible theories of causation and injury, without reference to the theories that they have developed and the gaps that remain, Petitioners' Motion has every indication of amounting to a request for leave to conduct a fishing expedition in an effort to save a failing causation case.[2]

Ignoring all of the publicly available evidence cited by Merck, Petitioners first misrepresent Merck's position by saying that Merck claims that "all of the evidence

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[2] Petitioners predictably bristled at the vaccine manufacturers' suspicion regarding the other possible reason for their seeking this subpoena: to get a head start on discovery in the high-stakes civil litigations that may lie ahead. (See Petitioners' Response at 11). Notably absent from Petitioners' response was an explanation for the patently irrelevant requests included in the initial proposed subpoena, identified by Merck in its Opening Brief. (See Merck's Opening Brief at 11, note 3.)

and information the Special Master needs is contained in discovery produced by the respondent in the omnibus proceeding." (Petitioners' Response at 3). As Merck made clear in its Opening Brief, it does not even know the contents of that discovery, a fact that underscores the unfairness of this entire subpoena process. Because Merck still does not know what Respondent has produced, it remains unable to address this one important area of the necessity picture. (See Section C, below). More to the point, however, Merck has made clear throughout that the Special Master should consider all of the evidence, including the best evidence: peer-reviewed published data addressing the alleged link between thimerosal and autism.

Building on their misstatement about the role that discovery provided by Respondent plays in Merck's position, Petitioners next argue that Respondent has admitted that there are "gaps in the scientific picture." (Petitioners' Response at 4).[3] To support this claim, which they make in December 2003, Petitioners cite to the IOM's report from October 2001, ignoring the abundant ensuing literature cited by Merck in its Opening Brief. As Petitioners point out, the IOM set out to study the alleged link between thimerosal-containing vaccines and autism-spectrum disorders. This panel of experts concluded that "the evidence is inadequate to accept or reject a causal relationship between exposure to thimerosal from vaccines and the neurodevelopmental disorders of autism, ADHD, and speech or language delay." (IOM Report at 4). Petitioners nevertheless filed these claims, presumably armed with expert opinion or data

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[3] Petitioners made no mention of these alleged gaps in their Motion papers. Thus, the notion that the "gaps" are what make manufacturer discovery necessary is newly minted.

that they believe supports a contrary conclusion, a fact totally at odds with their current lamentation that they have no case without manufacturer discovery.[4]

In its two-year old Report, the IOM did identify specific topics about which it recommended further epidemiological, clinical and basic science research. (IOM Report at 11). Between the date of the Report, and today, however, nearly a dozen research studies have appeared in peer-reviewed scientific journals addressing the topics identified by the IOM. See, e.g., Hviid, A., et al., Association Between Thimerosal-Containing Vaccine and Autism. *JAMA* (2003); 290; 13: 1763-1766; Verstraeten, T., et al., Safety of Thimerosal-Containing Vaccines: A Two-Phased Study of Computerized Health Maintenance Organization Databases. *Pediatrics* (2003); 112; 5: 1039-1048. (case control studies examining the potential link between neurodevelopmental disorders and thimerosal-containing vaccines); Madsen, K., et al., Thimerosal and the Occurrence of Autism: Negative Ecological Evidence From Danish Population-Based Data. *Pediatrics* (2003); 112; 3: 604-606; Stehr-Green, P., et al., Autism and Thimerosal-Containing Vaccines. *Am J. Prev. Med.* (2003); 25(2): 101-06 (epidemiological studies comparing prevalence of neurodevelopmental disorders before and after the removal of thimerosal from vaccines); Magos, L. Neurotoxic Character of Thimerosal and the Allometric Extrapolation of Adult Clearance Half-time to Infants. *J of Appl Toxicol* (2003) 23: 263-269; Pichichero ME, et al., Mercury concentrations and metabolism in infants receiving vaccines containing thimerosal: a descriptive study. *Lancet* (2002)

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[4] It is ironic that Petitioners now appear to embrace the IOM Report. The IOM's failure to find causation weighs heavily against Petitioners' prospects here. See Perez v. Secretary of Health and Human Servs., No.00-328V, 2003 WL 431593, at *9 (Jan. 14, 2003) ("While the special masters are not legally bound by the IOM reports, the IOM's conclusions have been afforded great deference and authority in vaccine cases given the IOM's congressional mandate and independent

360: 1737-41 (addressing how children metabolize and excrete thimerosal). In fact, subsequent to the publication of these research reports, the IOM decided to reconvene and is scheduled to meet on February 9, 2004, strongly suggesting that the IOM recognizes the importance of the recently published data.[5]

By imposing a necessity standard for Vaccine Court discovery, Congress contemplated that a precondition for discovery would be a genuine showing that the current record was inadequate. Although Petitioners claim to "seek only causation evidence relevant to the causation theory in the injuries at issue in the Omnibus Proceeding," (Petitioners' Response at 10), they nowhere identify what that theory is. If they have a theory, and there is a specific gap in that theory that they need to fill by accessing Merck's documents, then Petitioners should make the appropriate showing, identifying the gap, explaining why its filling is necessary for a fair resolution of their claims, explaining why it is not filled by the ample published literature, and explaining why it is necessary to burden Merck in their effort to fill it. See Allen v. Howmedica Leibinger, GmhH, 190 F.R.D. 518, 524 (W.D. Tenn. 1999) ("in order to determine ... if discovery is "relevant to the subject matter of the lawsuit," ... the plaintiff must, at a minimum, set forth a recognized damage theory ... [and] must enunciate some factual

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role in reviewing existing literature relating to the adverse consequences of vaccines"). See generally 42 U.S.C. § 300aa-13(a)&(b) (establishing a petitioner's burden of proving causation).

5 Petitioners also cite an FDA website in support of their argument about gaps in the scientific record. That site does state that more research may be warranted, but it was last updated in December, 2002, before all but one of the above-cited studies were published. The quoted language from the website identifies two areas for further research: 1) whether regressive autism is causally related to thimerosal in vaccines and 2) the synergistic biological interaction between aluminum and mercury in vaccine products. Many of the above-cited studies, all published in 2003, set out to examine the alleged link between autism and thimerosal-containing vaccines. If Petitioners' experts plan to rely on a theory regarding a purported unique effect of thimerosal on ***regressive*** autism, or on a theory that thimerosal in vaccines causes autism because of its synergistic interaction with aluminum, Petitioners need to submit affidavits from their experts to

support for the theory with some degree of particularity"). At that point, the Special Master could assess Petitioners' claim -- had they made one -- as to why that gap is so important and the answer lies so uniquely with Merck that Congress' objective of reducing vaccine manufacturer litigation burden should be overridden. Petitioners have simply failed to supply the Special Master with any of the factual predicates upon which he could find that further discovery is necessary.[6]

B. The Vaccine Act shields manufacturers from litigation, not just liability.

Even if Petitioners could show that more discovery was needed, they still would have to show why they need it from a vaccine manufacturer like Merck, whom the Vaccine Act was crafted to protect. Petitioners accuse the manufactures of having a "uniquely myopic vision of the legislative purposes of the Vaccine Act" (Petitioners' Response at 8), but it is they who have lost sight of Congress' intent. It is not true, as Petitioners would have it, that Congress' only goal in enacting the Vaccine Act was to hasten the resolution of vaccine-related injury claims. Congress also had (and clearly expressed) the goal of ensuring the country's vaccine supply by protecting manufacturers from the burdens of litigation – which includes more than just shielding manufacturers from potential damage awards.

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that effect, and then identify precisely the information related to those theories that they claim the Special Master needs and only the manufacturers have.

6 Wittner v. Secretary of Health and Human Services, 43 Fed. Cl. 199 (1999), the case that Petitioners rely upon, presents a much different situation than the one here. In Wittner, the Special Master permitted Respondent to call as a witness the pediatric neuorologist whom the petitioner claimed had served as his non-testifying expert. The court merely held that the neurologist's expertise, and the fact that he had treated the petitioner during five crucial years, made his testimony necessary to the Special Master's determination. Here, Petitioners have not identified any information that the Special Master needs that is known only to Merck, but instead ask for any evidence that might help them prove their claims.

Prior to enacting the Vaccine Act, the House Subcommittee on Health and the Environment was charged with conducting a study of the vaccine-shortage crisis that reached its peak in the 1980s. The reason for this study was to understand how the increase in litigation costs caused a dramatic increase in vaccine manufacturers' insurance costs and, in many instances, caused the insurance companies to deny coverage to some manufacturers, which in turn affected the vaccine supply. See Subcommittee on Health and the Environment, 99th Cong., Childhood Immunizations 1, 85-89 (Comm. Print 1986).[7]

Congress understood that if the manufacturers were forced out of business, the results would be disastrous. The legislative history of the Vaccine Act shows that Congress' concern extended to litigation expenses attributable to the costs of defending lawsuits as well as to expenses attributable to damage awards. Thus, contrary to Petitioners' argument, the Vaccine Act aimed not only to relieve manufacturers from burdensome damage awards, but also to ameliorate the general "litigation experience" of vaccine manufacturers, and to protect them from the burdens imposed by "the annual defense costs of vaccine injury litigation that was not reimbursed by insurance." Id. at 87; see also H.R. 99-908 (P.L. 99-660), at 7 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6348 ("Just as important, the Committee believes that once this [vaccine compensation] system is in place and manufacturers have a better sense of their potential litigation obligation, a more stable childhood vaccine market will evolve"). Congress was concerned about effects on the vaccine supply resulting from litigation costs

[7] This report is referenced in the House Report, as providing "a more detailed discussion of the litigation experience of manufacturers," which the House Report cites as an overarching focus of the Vaccine Act. H.R. 99-908 (P.L. 99-660), at 6 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6347.

associated with claims of injury allegedly caused by vaccination. To distinguish between litigation expense and liability expense in this context would be artificial and would carve out an exception that Congress did not intend.

Finally, Petitioners suggest that Merck would be to blame for the litigation burden associated with compliance with a subpoena, characterizing the manufacturers as the instigators of this discovery dispute and of the "collateral litigation over the issue of 'necessity.'" (Petitioners' Response at 12). That accusation has no merit. Merck is no more the instigator of this dispute than is any entity of whom an extreme demand is made, and then having refused to comply with the demand, finds itself hauled into court.

C. Merck has a right to see the discovery provided to Petitioners.

Merck requested access to the documents and data produced to Petitioners not (as Petitioners would have it) so that Merck could be the arbiter of whether third party discovery is necessary, but so that Merck could better address Petitioners' contentions about their need for more discovery. On November 25, 2003, the Special Master denied Merck's request, saying that he found Merck's arguments in support of its motion for access to be "logical and persuasive," but that such access was permissible only with the consent of the producing party (i.e., Respondent). As noted in the November 26, 2003 "Order re Merck's Motion for Information re Discovery," Petitioners voiced no objection to Merck's request: ("I note at the status conference held on November 25, 2003, the representative of the Petitioners' Steering Committee stated that the Committee would also have no objection to sharing the requested information with Merck")). Thus, although the Special Master denied Merck's motion, Merck still could gain access to the discovery if Respondent were to consent.

Petitioners' Response attempts to go back on that earlier position and to create roadblocks to Merck's request, while at the same time highlighting the unfairness of denying Merck access to the discovery they have received so far. Repeatedly, Petitioners claim that the evidence produced to date is insufficient. (See, e.g., Petitioners' Response at 3: "Petitioners would not seek the requested information from Merck . . . if the government documents produced so far in discovery provided the information needed to resolve the inquiry.") If Petitioners are going to justify their request for Merck's documents by arguing that those documents are necessary in light of "the paucity of the causation evidence produced by the government," (id.) it is only fair and reasonable to allow Merck access to government-produced evidence in order that it can adequately address Petitioners' argument. In any event, that issue is out of Petitioners' hands, as the decision whether Merck is to be allowed access is for Respondent to make.

II. Petitioners Fail To Explain Why They Have Singled Out Merck.

Petitioners dispute that they have singled out Merck for discovery, arguing that they plan to target all manufacturers eventually, and that the Special Master should address discovery disputes as they arise. Thus, Petitioners insist on requesting issuance of manufacturer subpoenas one at a time – an approach for which the Special Master has not expressed a preference (and it is his need, after all, not Petitioners' need, that drives the discovery process). Ostensibly, it was Petitioners' desire to hasten the discovery process that gave rise to the notion of third party discovery in the first instance. It is ironic, therefore, that Petitioners are taking this seriatim approach to the issuance of subpoenas, which undoubtedly will slow down the discovery process even more.

III. Petitioners Have No Right To Discover Merck's Trade Secrets.

In its Opening Brief, Merck made three points about its right to redact trade secret information in the PLAs. Petitioners' Response fails to address meaningfully any of Merck's arguments.

First, Merck stated that under no circumstance is a party entitled to discover trade secrets that are irrelevant to the issue in dispute.[8] Merck also noted that Petitioners had not argued that any of the information redacted from the PLAs was relevant to the causation issue. Petitioners respond by stating that they "do not concede" that all redacted information is irrelevant. (Petitioners' Response at 14). Yet Petitioners make no attempt to show or provide an example of potentially relevant trade secret redactions. Petitioners also have declined Merck's invitation to come forward with affidavits from experts as to what trade secret protected material they would need for their causation analysis. (See Merck's Opening Brief at 18, note 7.)

It is nearly impossible to imagine that the as-yet unidentified "gaps" in the undisclosed theories of Petitioners' experts as to why thimerosal in vaccines causes autism can be filled by information about manufacturing processes, quality control procedures, or any of the many details that permeate a PLA and that a vaccine manufacturer rightfully needs to protect. A finding, based on counsel's casual references to an unsubstantiated need for unidentified data, that these facially irrelevant materials are "necessary," not only would run afoul of even the most permissive standards of

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[8] This is true irrespective of whether the requesting and producing parties are business competitors. See In re Remington Arms Co., 952 F.2d 1029, 1032 (8th Cir. 1991) (a case not involving competitors): "If the party seeking discovery fails to show both the relevance of the requested information and the need for the material in developing its case, there is no reason for the discovery request to be granted, and the trade secrets are not to be revealed."

conventional civil discovery, but also would put at risk bedrock intellectual property assets that are critical to saving lives by maintaining the nation's vaccine supply.

Second, Petitioners say nothing in response to Merck's argument about the potential harm to the manufacturers as a result of disclosure of their trade secrets. Petitioners have yet to identify a need for the redacted information other than their desire to hasten the discovery process by receiving the PLAs in unredacted form. Even if a balancing test were appropriate in this situation (which it is not, because when the trade secrets in question are not relevant, there is nothing to balance against), the interest in protecting the trade secrets that make viable the nation's vaccine supply outweighs any interest that Petitioners have identified.

Third, Petitioners are silent about Merck's argument that their attempt to get unredacted PLAs from the manufacturers is an unprecedented and improper attempt to avoid statutory and court-imposed obligations and rights regarding redaction of trade secrets. As explained in Merck's Opening Brief (at 16-21), Congress and the courts have imposed limits on access to the PLAs that vaccine manufactures are required to submit to the FDA as part of the licensing process. See 18 U.S.C. § 1905; 21 U.S.C. § 331(j); 5 U.S.C. § 552(b)(4); 21 C.F.R. §§ 20.61(c) & 314.430; Chrysler Corp. v. Brown, 441 U.S. 281, 285, 318 (1979); Zeneca v. Shalala, No. WMN99-307, 1999 WL 167139, at **3-4 (D. Md. March 4, 1999); Serono Labs., Inc. v. Shalala, 35 F. Supp.2d 1, 4 (D. D.C. 1999) Congress and the courts have acted to protect manufacturer trade secrets in order to enable manufacturers to provide information to the licensing body, without fear of losing protection for their intellectual property assets. See Critical Mass Energy Project v. Nuclear Regulatory Comm'n, 975 F.2d 871, 872 (D.C. Cir. 1992). Nonetheless,

Petitioners suggest that all of the thousands of claimants, plus their lawyers and experts, should have free reign over the valuable trade secret assets that manufacturers are protected by law from having to disclose. Petitioners do not and cannot offer any justification for this demand.

Finally, Petitioners also fail to respond to either of Merck's alternative suggestions for speeding up the discovery process. Toward that end, Merck proposed 1) that Respondent produce the clinical data in the PLAs relating to safety first, (i.e., produce first those documents that are most likely to contain evidence about use of the vaccines in humans and few redactions)[9]; or 2) that Petitioners accept the PLAs as redacted by the manufacturers (thereby effectively eliminating the FDA as the middle-man with respect to redaction), and take up with the manufacturers any disputes regarding redaction as they arise. If the goal is to speed up the process, that goal can be accomplished without compromising the intellectual property assets of the vaccine manufacturers.

In lieu of addressing Merck's suggestions, Petitioners state that "at the very least, petitioners are entitled to the Special Master's *in camera* review of the redacted material for a determination of relevance." (Petitioners' Response at 14). That solution is not too different from what Merck proposed. Petitioners should review the redacted Recombivax PLA produced by Respondent and, if they identify redacted information that they think is relevant to the question of whether thimerosal in vaccines causes autism-spectrum disorders, they can submit an expert affidavit particularizing the trade-secret protected information that the FDA has redacted from the PLA, and

explaining why they need that information. Merck will then review the affidavit. If it cannot reach agreement with Petitioners, they can seek resolution of the dispute by the Special Master following *in camera* review of the redacted material.

CONCLUSION

For the reasons set forth above, in Merck's Opening Brief and Exhibits, and in the submissions of *amici curiae*, Petitioners' Motion should be denied.

Date: December 29, 2003

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[9] As noted earlier, Merck understands that this process, as a practical matter, is underway in that Respondent recently provided Petitioners with documents from the Recombivax HB PLA as to which there is no trade secret redaction dispute.

CERTIFICATE OF SERVICE

I hereby certify that on December 29, 2003, I served the foregoing **NON-PARTY MERCK & CO.'S REPLY TO PETITIONER'S RESPONSE RE NON- PARTY DISCOVERY** on the following individuals:

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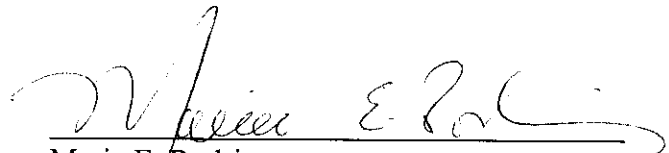

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