

CoMED INC.

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September 27, 2011

Béatrice Sloth
Head of Section
Secretariat for the
Danish Committees on Scientific Dishonesty
direct phone: +45 7231 8221
e-mail: bels@fi.dk

Dear Dr. Sloth

Thank you for your July 7, 2011 response to my Sept. 15, 2010 email and Nov. 24, 2010 email regarding the scientific misconduct of Dr. Poul Thorsen.

Dr. Thorsen was a “scientist in residence” at the United States Centers for Disease Control (CDC) between 2000 and 2002. At this time, the CDC was very concerned regarding the putative causal relationship between infant vaccinations and autism. In fact, the CDC commissioned the Institute of Medicine (a body independent of the U.S. Government and commercial interests) of the U.S. National Academy of Sciences to specifically investigate this issue.

In the summer of 2001, the Institute of Medicine (IOM) was about to issue a report stating that it had found the relationship between mercury exposure via Thimerosal-preserved vaccines and autism incidence to be biologically plausible, based on a comprehensive review of the most current scientific literature.

This decision was very unpopular within the CDC and chief scientists within the National Immunization Program (of the CDC) set out to find autism incidence and vaccine uptake data in other countries that might be able to be used to disprove such a causal relationship. As such, Dr. Thorsen was approached to serve as a liaison between the CDC and Denmark scientists to facilitate an investigation into the incidence of autism in Denmark after the phase out of Thimerosal-preserved vaccines in 1992.

After the relationship had been established with Dr. Thorsen in 2000, Dr. Diane Simpson, Acting Deputy Director of the National Immunization Program (NIP), contacted one of Thorsen’s colleagues in Denmark, Dr. Kreesten Madsen to access autism incidence data, in hopes that the causal relationship between thimerosal containing vaccines and autism could be disproven [see **Exhibits 1 and 2**]. Dr. Simpson specifically asked whether autism incidence rates went up in the 1990’s and Dr. Madsen replied that they had gone up only slightly and that this could be explained by varying diagnostic criteria used to account for autism cases and by the inclusion of outpatient clinics in counting these cases starting in 1995 [see **Exhibit 1**]. Denmark had phased out Thimerosal-preserved vaccines in 1992 and the CDC was looking for data that showed a significant increase in autism rates after this date [see **Exhibit 1**], which could be used to disprove the “autism-thimerosal” theory, and the Danish researchers involved obviously tried their best to generate a paper that provided what the CDC wanted.

Despite the fact that autism rates did not increase dramatically after 1992, Dr. Simpson visited Denmark in August, 2001, and entered into a collaboration with scientists at Aarhus University (including Dr. Thorsen). This led to the publication of the paper, “Thimerosal and

the occurrence of autism: negative ecological evidence from Danish population-based data” that appeared in the journal *Pediatrics* in 2003 [Madsen KM, Lauritsen MB, Pedersen CB, Thorsen P, Plesner A-M, Andersen PH, Mortensen PB. Thimerosal and the Occurrence of Autism: Negative Ecological Evidence From Danish Population-Based Data. *Pediatrics* 2003 Sep; 112(3): 604 -606].

Based on redacted copies of pertinent e-mails obtained from the CDC under the US Freedom of Information Act (FOIA), it was clear that Dr. Poul Thorsen:

- Knew, *contrary to the paper’s assertions*, that the “incidence and prevalence” rates for autism had dropped after the removal of the Thimerosal-preserved (“Thimerosal-containing”) vaccines from the Danish vaccination program in 1992 (see **Exhibit 3**), and
- Acted to facilitate the publication of a knowingly misleading article (see **Exhibit 4**).

From the context of the **Exhibit 3**’s e-mail, it is clear that, at a minimum, Kreestenn Meldgaard Madsen, Marlene Brieciet Lauritsen, and Poul Thorsen knew that the autism rates declined after the Thimerosal-containing vaccines were withdrawn from the Danish vaccination program as did the CDC (Diana M. Schendel).

The Madsen et al. (2003) paper was riddled with severe methodological flaws and the purported increases in autism rates in Denmark may be explained by three phenomena that occurred after 1992, when Thimerosal-containing vaccines were phased out of the Danish vaccination program.

1. First, the National Center for Registry Based Research (NCRB), which stewarded the autism incidence data, changed accounting methods and started counting autism cases based on outpatient visits in 1995 [see **Exhibit 1**], whereas, before this date, only inpatient (hospital) visits were recorded. This alone led to an estimated 13.5-fold increase in autism cases as reported in Madsen et al. (2002) [*NEJM* 2002; **347**: 1477].
2. Second, in 1994, the NCRB changed diagnostic criteria for autism from ICD8 (psychosis infantilis posterior) to ICD10 (infantile autism) [see **Exhibit 1**]. This alone would lead to an approximate 5-fold increase in autism cases based on the estimation presented in Trelka and Hooker (2004) [Trelka JA, Hooker BS. Correspondence: More on Madsen’s Analysis. *J Am Physicians Surgeons* 2004 Winter; **9**(4): 101].
3. Finally, the authors of the Madsen et al. (2003) publication neglected to account for the inclusion of a large outpatient clinic in Copenhagen in 1992, which accounted for 20% of the autism cases nationwide [Trelka and Hooker (2004)].

Taken together, these three confounding factors account for the entire increase in autism diagnoses after 1992. In fact, one comprehensive review of the data as published showed that autism rates could have *decreased* after 1992 by as much as 75% [Trelka and Hooker (2004)]. The authors (including Thorsen) appear to have obfuscated the underlying trends in the data by neglecting these three factors in their analysis. This led to one journal’s outright rejecting the manuscript for publication.

After this, Dr. Thorsen contacted CDC researcher Dr. Diana Schendel to recruit Dr. Jose Cordero, the then Director of the National Center for Birth Defects and Developmental

Disabilities of the CDC, to write a recommendation letter for expedited publication of the paper in the journal *Pediatrics*.

The most egregious example of misconduct was carried out in the data analysis leading to the Madsen et al. (2003) publication. In a Nov. 13, 2002 email correspondence obtained from the CDC via the Freedom of Information Act, Dr. Marlene Lauritsen, co-author of the publication, stated that the autism rates between 1999 and 2001 were actually decreasing.

Regarding the autism rates, Dr. Lauritsen stated, “But the incidence and prevalence rates are still decreasing in 2001” [see **Exhibit 3**]. These data did not support the assertion of the paper that thimerosal exposure was not causally related to autism. However, the final version of the published article did not include any of the 2001 data. The inclusion of this data would have, *at a minimum*, nullified the conclusions of the paper and could have indeed reversed them, showing a causal relationship between Thimerosal exposure and autism incidence in Denmark.

There have been several requests for the original data in order to repeat this study. However, the data have never been released to the public. Most notably, researchers Dr. Brian Hooker and Mr. Jeffrey Trelka (Autism Healing Network) submitted a letter to the editor of the journal *Pediatrics*, rebutting the Madsen et al. (2003) publication. Upon receipt, the editor of the journal forwarded the letter to the co-authors, who chose not to respond. This lack of transparency on the part of the Madsen et al. (2003) publication authors is, *at a minimum*, curious, especially considering the severe methodological flaws in the published paper.

To summarize, in the Madsen et al. (2003) paper, Dr. Poul Thorsen apparently colluded with several of his co-authors to withhold data that does not support the published paper’s conclusions, apparently conspired to misrepresent the reported data to lead readers to believe that the autism rates in Denmark increased dramatically after 1992 when they actually decreased, and apparently conspired to conceal the role of the CDC in producing this publication as shown by the e-mails in **Exhibits 1-5**.

Respectfully yours,



Rev. Lisa K. Sykes,

President, **CoMeD**

e-mail: Lisa@Mercury-freeDrugs.org

cc: Dan R. Levinson

Inspector General, Office of the Inspector General, US Department of Health and Human Services (HHS)

Email: dan.levinson@oig.hhs.gov

Pia Olsen Dyhr

Danish Parliament Member

Email: Pia.Olsen.Dyhr@ft.dk

Exhibit 1

Documents from US CDC FOIA Requests: Diane M Simpson's Copy of E-mail Stream:

Starting with last:

From: Simpson, Diane M.
Sent: Thursday, June 14, 2001 8:17 AM
To: 'Kreesten Meldgaard Madsen'
Subject: RE: autism data

Summary of the Critical Issues

Overall, this communication string establishes that the “true” Danish incidence and prevalence rates for autism: **a)** were not changing dramatically and **b)** the apparent changes were probably attributable to changes in the diagnostic criteria (ICD8 vs ICD10) and the inclusion of outpatient-clinic data “from 1995” as follows:

After introductory e-mails on 12 June 2001 from Diane M. Simpson (CDC) and 13 June response on 13 June 2001, Simpson asks Madsen in “13. juni 2001 13:58” e-mail, “RE: autism data”:

“... Out' primary question is: did the rates increase dramatically from the late 1980's into the 1990s as they did in the United States. A quick answer to that question would mean a great deal to us here!!! (even without specific numbers)”

Madsen's “Wednesday, June 13, 2001 8:07 AM” response:

“To the best Of my knowledge - no, the rates did not increase dramatically in the late 1980's. I am not sure the rates increased at all before 93.”

Simpson's “13. Juni 2001 14:19” email asked:

“Did they increase after 1993?”

Madsen's “Thursday, June 14, 2001 6:45 AM” email answered:

“Yes but not very dramatically and there could be reasons for that. First of all we had a change from ICD8 to ICD10 in 1994 and furthermore our outpatient clinics were registered in our surveillance from 1995. But I do not have the data here, so this is from my memory.”

Simpson's “Thursday, June 14, 2001 8:17 AM” email responded:

“Thanks for what you have thus far. Please let me know whenever you hear from the author of the paper on the autism rates whether he will share this data with us.”

Simpson, Diane M

From: Simpson, Diane M.
Sent: Thursday, June 14, 2001 8:17 AM
To: 'Kreesten Meldgaard Madsen'
Subject: RE: autism data

Thanks for what you have thus far. Please let me know whenever you hear from the author of the paper on the autism rates whether he will share his data with us.

-----Original Message-----

From: Kreesten Meldgaard Madsen [mailto:KMM@SOCI.AU.DK]
Sent: Thursday, June 14, 2001 6:45 AM
To: 'Simpson, Diane M.'
Subject: RE: autism data

Yes but not very dramatically and there could be more reasons for that. First of all we had a change from ICD8 to ICD10 in 1994 and furthermore our outpatient clinics were registred in our surveillance from 1995. But I do not have the data here, so this from my memory.

Best regards

Kreesten

-----Original Message-----

From: Simpson, Diane M. [mailto:dms3@cdc.gov]
Sent: 13. juni 2001 14:19
To: 'Kreesten Meldgaard Madsen'
Subject: RE: autism data

Did they increase after 1993??

-----Original Message-----

From: Kreesten Meldgaard Madsen [mailto:KMM@SOCI.AU.DK]
Sent: Wednesday, June 13, 2001 8:07 AM
To: 'Simpson, Diane M.'
Subject: RE: autism data

To the best of my knowledge - no, the rates did not increase dramatically in the late 1980's. I am not sure the rates increased at all before 93.

Best regards

Kreesten

-----Original Message-----

From: Simpson, Diane M. [mailto:dms3@cdc.gov]
Sent: 13. juni 2001 13:58
To: 'Kreesten Meldgaard Madsen'
Subject: RE: autism data

Thank you very much. Our primary question is: did the rates increase dramatically from the late 1980's into the 1990s as they did here in the United States. A quick answer to that question would mean a great deal to us here!!! (even without the specific numbers)

-----Original Message-----

From: Kreesten Meldgaard Madsen [mailto:KMM@SOCI.AU.DK]
Sent: Wednesday, June 13, 2001 4:51 AM

To: 'Simpson, Diane M.'
Subject: RE: autism data

Dear Diane Simpson,

An article is soon to be published on secular trends in the incidence and prevalence of autism in Denmark. The work was started before I started working with autism six months ago and I have not been part of that. I shall ask the author how far they are in the process and what I can mail to you. I now have a copy of the autism data myself but have only looked at it briefly. The prevalence (my rough calculations) is around 7-9 pr. 10.000 in the mid nineties.

Best regards

Kreesten

-----Original Message-----

From: Simpson, Diane M. [mailto:dms3@cdc.gov]
Sent: 12. juni 2001 17:27
To: 'kmm@dadlnet.dk'
Subject: autism data

Doctor Madsen,

Your name was given to me by our new Center for Birth Defects and Developmental Disabilities. I am the acting deputy for the National Immunization Program and need to find whatever data may exist on autism rates in children in Denmark over the last 20 years. As always, I need the data sooner rather than later. Any assistance you can provide would be greatly appreciated.

Exhibit 2

Documents from US CDC FOIA Requests: Diane M Simpson's Copy of E-mail:

From: Simpsom, Diane M.
Sent: Friday, August 17, 2001 8:31 AM
To: 'pbm@ncrr.au.dk'
Subject: RE: FW: visit to Denmark

Summary of the Critical Issues

The most recent “----Original Message----”, dated: “Friday, August 17, 2001 4:19 AM”, from: Preben Bo Mortensen [mailto: pbm@ncrr.au.dk] (of the National Center for Register-based Research), to: Simpson, Diane M., subject: Re: FW: visit to Denmark, which clearly shows that the CDC (Diane M. Simpson, a CDC employee, and Paul (Stehr-Green), a CDC consultant) were meeting on Friday 24 August, 2001 to discuss speeding “up publication of the autism-rates (treated incidence and prevalence 1971-2000) in connection with data on thimerosal use in Denmark” with “Poul” (Thorsen) and “Kreesten” (Madsen) and an unidentified “doctoral student”. [Note: This meeting is One of the antecedent events for the published paper: “Kreesten M. Madsen KM, Lauritsen MB, Pedersen CB, Thorsen P, Plesner A-M, Andersen PH, Mortensen PB. Thimerosal and the Occurrence of Autism: Negative Ecological Evidence From Danish Population-Based Data. *Pediatrics* 2003 Sep; 112(3): 604 -606”.]

The earlier “Simpson, Diane M.” message:

> I re-read an earlier email from Dr. Michael Stellfeld at the SS1 . He
> had written that Monday, Aug 27 would be the best day t o meet with him
> and his staff. Could we, therefore , meet with you on Friday, August
> 24?”,

clearly indicating that the CDC personnel were meeting with a vaccine manufacturer's employee who also happens to be one of the authors in another “Thimerosal-autism” paper [see: Stehr-Green P, Tull P, Stellfeld M, Mortenson P-B, Simpson D. Autism and thimerosal-containing vaccines: Lack of consistent evidence for an association. *Am J Prevent Med* 2003 Aug; 25(2): 101-106].

Simpson, Diane M

From: Simpson, Diane M.
Sent: Friday, August 17, 2001 8:31 AM
To: 'pbm@ncrr.au.dk'
Subject: RE: FW: visit to Denmark

Thank you. Paul and I will see you on Friday August 24 at 2PM. Neither of us have been to Denmark, so the fact that you are distant from Copenhagen will allow us to see more of your country.

-----Original Message-----

From: Preben Bo Mortensen [mailto:pbm@ncrr.au.dk]
Sent: Friday, August 17, 2001 4:19 AM
To: Simpson, Diane M.
Subject: Re: FW: visit to Denmark

Dear Dr. Simpson

Thank you for your mail. You would be welcome to visit Friday August 24. Unfortunately I already have a number of meetings sceduled, but I will be free at 2 pm. We are located in Aarhus, about 3 hours by train or a little less by air, from Copenhagen. Our address is below, and I'll be happy to send further directions when I know your exact plans. About the data I have discussed this with the doctoral student as well as Poul and Kreesten, and we have decided to try to speed up publication of the autism-rates (treated incidence and prevalence 1971-2000) in connection with data on thimerosal use in Denmark. I'll try to have a draft paper ready for you by Friday 24. We could then discuss the results as well as how to proceed with the publication process. Best wishes Preben Bo Mortensen

"Simpson, Diane M." wrote:

> I re-read an earlier email from Dr. Michael Stellfeld at the SSI. He
> had written that Monday, Aug 27 would be the best day to meet with him
> and his staff. Could we, therefore, meet with you on Friday, August
> 24?

> > -----Original Message-----

> > From: Simpson, Diane M.
> > Sent: Thursday, August 16, 2001 1:08 PM
> > To: 'pbm@ncrr.au.dk'
> > Subject: visit to Denmark

> > Dr. Mortensen,

> > Dr. Paul Stehr-Green and myself have finally received permission to
> > travel to Denmark and meet with you and your staff regarding your
> > autism data. We are looking forward to be able to speak with you
> > in-person. I believe our previous telephone call included the
> > reasons why we are seeking data on autism but I will be happy to
> > answer any questions you may have.

> > Paul and I will be leaving the US the evening of August 22 and will
> > arrive in Copenhagen around noon on August 23. (I must travel on
> > August 21, so August 20 will be my last day in the office before the
> > trip to Denmark)

> > We will be in Denmark all day on Friday, August 24 through late
> > afternoon on Monday 27. Will there be a convenient time to meet
> > with you and/or your student about your registry's data? Will you
> > please send us the address of your office?

> > I am also trying to arrange a visit with persons at the SSI during
> > the time that we are there to learn more about vaccines and vaccine-
> > coverage in Denmark. I do not know yet what time or day will be

> > convenient for them.

> >

> > Thank you for your assistance. I look forward to meeting with you.

--

Preben Bo Mortensen
National Center for Register-based Research
Tåsingegade 1
8000 Århus C
Tel: (+45) 89 42 68 20
Fax: (+45) 89 42 68 13
E-mail: pbm@ncrr.au.dk
Web-address: www.ncrr.au.dk

Exhibit 3

Documents from US CDC FOIA Requests: Diana Schendel's Copy of E-mail:

From: Kreesten Meldgaargd Madsen [KMM@SOCL.AU.DK]
Sent: Wednesday, November 13, 2002 5:33 AM
To: Marlene Brieciet Lauritsen; Poul Thorsen; Schendel, Diana
Subject: RE: Manuscript about Thimerosal and autism

Summary of the Critical Issue

The “----Original Message----”, dated: “Wed 13 11 2002 09:24”, from: Marlene Brieciet Lauritsen, (mailto: mbl@dadlnet.dk), to: Poul Thorsen, Kreesten Meldgaargd Madsen and dcs6@cdc.gov, subject: Manuscript about Thimerosal and autism, which, when speaking of autism in Denmark, clearly states: “But the incidence and prevalence are still decreasing in 2001”.

Thus, all of these individuals, Kreesten Meldgaargd Madsen, Marlene Brieciet Lauritsen, Poul Thorsen, and Diana Schendel, knew by the end of November 13, 2002, *if not before*, that the removal of the Thimerosal-preserved DTP vaccine from the Danish vaccination program had led to a decrease in the “incidence and prevalence” of autism in Denmark. Yet they all colluded with the US Centers for Disease Control and Prevention to submit a document for publication that made a knowingly false claim that the “rate” of autism increased after the Thimerosal-preserved vaccines were withdrawn for use in Denmark.

10-05-2005 02:55pm From-

T-923 P.002/028 F-345

Schendel, Diana

ORIGINAL EDITED
FILE COPY
DO NOT RELEASE

From: Kreesten Meldgaard Madsen [KMM@SOCI.AU.DK]
Sent: Wednesday, November 13, 2002 5:33 AM
To: Marlene Briclet Lauritsen; Poul Thorsen; Schendel, Diana
Subject: RE: Manuscript about Thimerosal and autism

Hi Marlene,

[REDACTED]
[REDACTED] I am not currently at the
university but I will contact you and Poul tomorrow to make up our minds. Best regards,
Kreesten

-----Original Message-----
From: Marlene Briclet Lauritsen [mailto:mb1@dadlnet.dk]
Sent: Wed 13-11-2002 09:24
To: Poul Thorsen; Kreesten Meldgaard Madsen; dcs6@cdc.gov
Cc:
Subject: Manuscript about Thimerosal and autism

Dear Poul, Kreesten and Diane Schendel
Attached I send you the short and long manuscript about Thimerosal and autism in
Denmark. [REDACTED]

I need to tell you that the figures in the manuscripts do not include the latest
data from 2001. I only have these figures as a paper version and they are at work [REDACTED]
[REDACTED] But the incidence and prevalence are still decreasing in
2001. [REDACTED]

I look forward to hear from you again.
Best regards
Marlene

Exhibit 4

Documents from US CDC FOIA Requests: Redacted Poul Thorsen E-mail:

From: Poul Thorsen [mailto: pt@SOCLAU.DK]
Sent: Tuesday, November 26, 2002 6:02 AM
To: Schendel, Diana
Subject: Autism thimerosal cover letter

Summary of the Critical Issue

This e-mail confirms Dr. Thorsen's role in getting article published as well as the assistance the CDC was providing to get the article published as soon as possible in 2003.

Poul Thorsen's request : "... Could you or Coleen write a cover-letter underlining the importance of getting this information out now? Please do not mention the Journals name, as it is not finalized, <redacted> Could you bring this letter with you when you come? See you soon"

-----Original Message-----

From: Poul Thorsen [mailto:pt@SOCI.AU.DK]
Sent: Tuesday, November 26, 2002 6:02 AM
To: Schendel, Daana
Subject: Autism thimerosal paper - cover letter

Dear Daana,

1

10-03-2005 02:26pm From-

T-915 P.003/006 F-331

Here are the latest versions and the figure still need to be updated, but will be. Marlene believes ~~_____~~ Could you or Coleen write a cover-letter underlining the importance of getting this information out now? Please do not mention the Journals name, as it is not finalized, ~~_____~~ Could you bring the letter, when you come? See you soon!

Thank you!

Best regards
Poul

skype

Wayne Mayhew

Exhibit 5

Documents from US CDC FOIA Requests: Cordero Letter to Editor in Chief, Pediatrics:

Summary of the Critical Issue

Letter shows the CDC's use of influence at a high level (United States Assistant Surgeon General) to get this knowingly biased study published:

"Sincerely,

<S>

José F. Cordero, M.D., M.P.H.
Assistant Surgeon General
Director
National Center on Birth Defects
and Developmental Disabilities"

The letter cleverly states

"In addition, a key strength of the study is the ability to examine rates of autism prior to and after the discontinuation of vaccines containing thimerosal in Denmark in 1992. Contrary to what would be expected if thimerosal was linked to autism, the authors did not observe a decline in the rate of autism with the removal of thimerosal containing vaccines."

In addition, the letter closes with:

"I feel this is a very important study that deserves thoughtful consideration by the Journal. Its findings provide one strong piece of evidence that thimerosal is not causally linked to autism. Thank you for your timely consideration."



Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30341-3724

December 10, 2002

Jerold F. Lucey, M.D.
Editor in Chief
PEDIATRICS
University of Vermont
College of Medicine
Pediatrics Editorial Office
89 Beaumont Avenue, GIVEN D201
Burlington, Vermont 05405 - 0068

Dear Dr. Lucey:

I am writing in support of an expedited review and consideration of the enclosed manuscript that examines the association between thimerosal, an ethyl mercury containing preservative, and autism. As you may know, there has been considerable interest by parents, clinicians, educators, and policy makers for an explanation of the marked increase in the rate of autism in recent years. A University of Davis study released in October of children identified through the California developmental disabilities service system, reemphasized the upward trend in autism and the lack of understanding as to the cause.

One factor hypothesized to have a causal role is childhood vaccinations. Specific aspects of vaccinations that have been subject to inquiry include the MMR vaccine and thimerosal. There are now numerous epidemiologic studies to suggest that the MMR vaccine is not associated with the risk of autism; an Institute of Medicine review that was published in 2000 concluded that the weight of the scientific evidence did not support a link between MMR vaccine and autism.

For thimerosal, however, there are limited data to evaluate this factor. Because mercury in its inorganic form is known to have serious neurologic effects, many parents have speculated that the increased number of vaccines (many of which contained thimerosal) may have been a significant factor in the recent rise in autism. The Danish study is a powerful epidemiologic study of this issue and capitalizes on the Danish health registry system that incorporates all health encounters into disease and exposure specific registries. In addition, a key strength of the study is the ability to examine rates of autism prior to and after the *discontinuation* of vaccines containing thimerosal in Denmark in 1992. Contrary to what would be expected if thimerosal was linked to autism, the authors did not observe a decline in the rate of autism with the removal of thimerosal containing vaccines.

Page 2 - Dr. Jerold F. Lucey, Editor in Chief, PEDIATRICS

I feel this is a very important study that deserves thoughtful consideration by the Journal. Its findings provide one strong piece of evidence that thimerosal is not causally linked to autism. Thank you for your timely consideration.

Sincerely,

A handwritten signature in black ink, appearing to read 'Jose', written in a cursive style.

José F. Cordero, M.D., M.P.H.
Assistant Surgeon General
Director
National Center on Birth Defects
and Developmental Disabilities