Testimony of
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before the
House Subcommittee on Energy and Environment

"The Assistance, Quality, and Affordability Act of 2010"
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Thank you for inviting me to testify. I am pleased to have this opportunity to address the recently introduced Bill that would, among other things, amend the Estrogenic Substances Screening Program provisions of the Safe Drinking Water Act. 42 U.S.C. §300j-17. My testimony addresses only Section 16 (Endocrine Disruptor Screening Program) of the Assistance, Quality, and Affordability Act of 2010 (the "Act").

Background

I am an attorney with a toxicology background. For the last 15 years I have addressed legal, regulatory, scientific and policy issues related to the endocrine issue and to the development and implementation of EPA's Endocrine Disruptor Screening Program (EDSP). During this time I have represented various sectors of the chemical industry. In my regulatory and litigation practice I address issues that arise at the intersection of science and law. Endocrine disruption is one of those many legal/science issues I have addressed in my years of practice.

I represent only myself today. My testimony is based on my legal and scientific training and expertise, my own experiences concerning endocrine legislation and regulatory activities, and my experiences concerning the potential effects of regulation on the affected community.

General Observation

While I understand the concern of the Subcommittee regarding the pace at which the EDSP has been developed and implemented and the Subcommittee's desire to push forward with a Bill to speed up testing of chemical substances (especially those that may be found in drinking water), I am concerned that various provisions of the Bill are contrary to good science, fail to require the use of good science and either intentionally or unintentionally significantly undermine existing, well-established procedures for science-based regulation. In that regard, I believe significant improvements can and should be made to the Bill to ground it

more on objective principles of science. I suggest a number of areas of improvement in the following section of my testimony.

This Subcommittee heard testimony on February 25, 2010 and Health Subcommittee heard testimony on April 22, 2010, concerning the basic scientific principles applicable to endocrine screening. While not new, those principles were well summarized by Dr. Borgert at the February 25th hearing. Briefly, those principles concern: (1) measurement: scientific studies must measure what they claim to have measured within a known margin of error; (2) confounding: measurements and observations must not be confounded by extraneous factors and influences known to corrupt their accuracy and precision; and (3) replication: measurements and observations must be replicable in independent hands. At the April 22nd hearing, Dr. Birnbaum of NIEHS and Dr. Falk of ATSDR agreed that "good science" includes these principles and that "regulatory policy in the United States, things that we do, to the extent that it is going to rely on scientific research should, at a minimum, make these criteria . . . the cornerstone of our policymaking." April 22, 2010 Hearing on "The Environment and Human Health: HHS' Role" at 79-80. When I refer to "good science" in my testimony I am referring to these and related scientific principles. For purposes of this statement, I would add other scientific concepts such as the need to weigh and consider all data when forming broader scientific conclusions or managing risks. I also believe it is important to understand to what extent certain data and observations are relevant to answering broader scientific questions (such as whether a substance is an "endocrine disruptor" or whether a substance may pose a risk to human health or the environment) and to managing related potential risks. Generally, I have been concerned that many involved in the endocrine disruptor issue often fail to adhere to the above-mentioned scientific principles, fail to consider all the data, and often misstate the relevance of data upon which they rely.

Section 300j-17 of the Safe Drinking Water Act currently grants EPA the Authority to accomplish most if not all of the activities provided in the Bill. An obvious feature of the Bill is that it directs EPA to list and order testing of substances that may be found in sources of drinking water. More significantly, the Bill sets deadlines for those activities. Those deadlines, while understandable, may lead to unnecessary endocrine screening that could waste limited resources and lead to the unnecessary use of a great number of laboratory animals. For that reason, I believe the deadlines in the Bill should be slightly revised to allow EPA to modify, to the extent necessary and consistent with scientific principles, its Tier 1 screens and screening battery before undertaking additional screening.

Less obvious are a variety of other provisions and the use of various terms in the Bill that may significantly undermine the well developed scientific process currently used for science-based regulation in the United States. It is not clear whether those provisions are intentional or merely an artifact of legislative drafting. Specifically, health-based chemical regulation in the US currently is

based on the potential for substances to produce adverse affects. As discussed below, the Bill appears to suggest that EPA may and possibly should regulate based on a substance's mechanism or mode of action, regardless of whether that mechanism is adverse or leads to an adverse effect. Again, it is unclear whether it is the intent of the Bill to create a new regulatory paradigm. In any event, consistent with well-established principles for conducting risk-based regulation and with principles of sound science, the Bill should be modified to clearly state that to the extent EPA manages (i.e., regulates) endocrine disruptors, that regulation should be risk-based and designed to manage adverse effects.

Suggested Improvements to the Act

1. EPA should be allowed to complete its initial phase of screening before it is required to issue additional testing orders.

As the committee learned from the testimony it heard at its February 25, 2010 hearing, the time it has taken EPA to develop and implement its EDSP was expected by scientists given the Agency's attempt to develop and implement a very ambitious program along with the need to develop and validate a large number of new assays. Even at this time there remains significant uncertainty as to how well the individual assays and the Tier 1 EDSP battery will perform. Because of the uncertainties related to the Tier 1 screens and battery, EPA's Science Advisory Panel recommended that EPA initially undertake screening of fewer than 100 chemicals and, based on the results and experiences for those chemicals, modify Tier 1 screens and the Tier 1 battery as necessary prior to undertaking additional screening. Indeed, the initial phase of EDSP screening will be necessary to evaluate the performance of the screening assays and to validate the Tier 1 battery. The expectation of the SAP was that additional screening would not commence until after the first phase of screening was completed and assessed, and necessary changes were made to the assays and battery.

The Bill would require EPA to issues one or two rounds of new screening orders prior to its completion and assessment of the initial phase of screening. The Subcommittee should realize that, to the extent modifications to the Tier 1 assays and battery will need to be made in response to problems uncovered in the initial phase of screening, additional screening conducted prior to those modifications could result in a waste of limited resources and the unnecessary use of laboratory animals.

It will take two years from this point for EPA to complete the initial phase of screening under the EDSP and to analyze the data generated by that screening. During that time EPA should work diligently to develop a weight of evidence process for assessing Tier 1 screening data. I believe it would be more scientifically sound for the Act to require additional screening after that two-year

period and to direct EPA to develop its weight of evidence assessment procedures within one year so that those procedures are available as data from Tier 1 screening are reported.

2. The Bill should define "endocrine disruptors" as substances that exert an adverse effect.

The Bill changes the current definition of "endocrine disruptors" used in EPA's EDSP. The current definition of endocrine disruptor includes the concept of adverse effect (i.e., "endocrine disruptors" are currently viewed as substances that cause adverse effects through interactions with the endocrine system). The Bill's new definition is sufficiently broad to label anything that interacts with the endocrine system, regardless of effect, an "endocrine disruptor." In effect, the new definition would result in labeling anything screening positive in EDSP Tier 1 screening an "endocrine disruptor." It is unclear whether this is the intent of the Bill.

The Subcommittee should realize that the Bill's new definition would include within the term "endocrine disruptor" substances in the diet such as soy, sugar, salt, vegetables and almost all other exposures including physical factors such as sunlight. It should be remembered that the endocrine system functions as a mechanism to maintain homeostasis. Almost any exposure, given the right dose, will elicit adaptive changes in the endocrine system. Most of those changes are normal and without adverse effect. For these reasons, the Bill's new definition of endocrine disruptor is so broad as to be meaningless and useless. My concern is that the term "endocrine disruptor" is often used to elicit emotional responses that are not supported by the science. Indeed, how can the average person believe that the term "disruption" is not bad or adverse, even when endocrine disruption refers to a normal, uneventful interaction. In sum, the Bill's new definition of "endocrine disruption" implies adversity when there may be no adversity.

I believe the definition of "endocrine disruptor" in the Bill should be modified to read: " 'Endocrine disruptor' is an exogenous agent or mixture of agents **that causes an adverse effect by** interfer**ing with** or alter**ing** the synthesis, secretion, transport, metabolism, binding action, or elimination of hormones . . . ." Again, in my view, without this modification the Bill's definition of endocrine disruption is meaningless, useless and likely to cause mischief.

3. The Bill appears to promote regulation based on mechanism or mode of action.

When viewed in its entirety, the Bill appears to promote, contrary to currently established scientific and regulatory principles, regulation based simply on a substance's mode or mechanism of action. It is unclear whether this result is intended. In any event, the Bill plows new ground in this regard – we generally do not regulate based on mechanism. Rather, chemical regulation in the US is

generally based on the potential for a chemical to cause adverse effects on humans or the environment. My view is that the Bill should not promote regulation based solely on mechanism of action. I believe for a variety of reasons that such regulation would be contrary to good science and sound regulatory policy. It would also set a dangerous precedent that could affect all agency action.

My concerns arise out of the Bill's new definition of "endocrine disruptor" which appears to over emphasize the relevance of mechanism and ignores the importance of adverse effects. Further the Bill's definition of "testing" fails to distinguish the important difference between, and respective relevance of, screening and testing. Finally, the Bill explicitly directs EPA to determine whether to take action on "testing results" within 6 months after receipt of those results. See Section 1457(f)(2). Given the definition of "testing," which includes screening, and the fact that for most compounds EPA will have only screening data within 6 months of receiving "testing results," it appears the Bill may envision regulation based on screening results (i.e., mechanistic data) alone.

For the above reasons, I believe the Bill should be modified to (1) include the concept of adverse effects in the definition of "endocrine disruptor"; (2) distinguish screening and testing in the definition of "testing" and throughout the Bill to the extent necessary; and (3) clearly state in Section 1457(f)(2) that regulation should be risk-based and designed to manage adverse effects consistent with the current regulatory approach. As currently written, the scientific basis for various provisions in the Bill appear, at best, garbled and may lead to interpretations of the Bill contrary to Congressional intent. At worst, the Bill may actually intend to create a new regulatory paradigm unsupported by science and good regulatory policy.

I believe modifications to the Bill should be informed by a number of basic scientific and policy concepts upon which the EDSP and science-based chemical regulations are based. These concepts have been extensively discussed by the National Academy of Science, other scientific bodies and by various scientists. First, it is important to understand that screens are not tests. Screens are designed to be very sensitive and, therefore, generally have high false positive rates. Screens are useful to prompt testing. In the case of the EDSP, Tier 1 screening is designed to identify substances that may interact with the endocrine system and, in that regard, prompt more definitive Tier 2 testing. Tier 1 screens are not useful, on their own, for determining hazard or as a basis for regulation. Tests, however, can determine the potential for adverse effects and can serve as the basis for determining hazard. It is important to note, however, that identifying hazard is not equivalent to testing. Hazard is identified after testing data are interpreted using a weight of evidence assessment. Hazard, while not sufficient in itself for assessing risk, is used along with exposure data to assess risk. Finally, risk assessment, along with consideration of various societal issues, forms the basis for regulation.

4. All scientifically relevant information should be considered when ordering EDSP screening and testing.

Focusing on what should be the ultimate goal of the EDSP – determining which substances have the potential to cause adverse effects and managing associated risks – Congress may want to take this opportunity to clearly direct EPA to utilize, to the greatest extent possible, existing data that examines potential adverse effects. In that regard, it may be possible for some chemicals to forgo Tier 1 screening when sufficient Tier 2 type data are available. Although in some of these cases complete mechanistic data may not be available (data that might be generated in Tier 1 screening), sufficient data may still exist for purposes of assessing and managing risks. Therefore, while mechanistic data may be interesting in these cases, it may not be necessary for achieving the ultimate goal of the EDSP. By eliminating unnecessary screening and testing it may be possible to redirect limited resources to substances for which there exists fewer relevant data. Eliminating unnecessary screening and testing may also decrease the use of laboratory animals and further animal welfare concerns.

5. Throughout the Bill, EPA should be reminded to use the minimum criteria for developing reliable and relevant scientific information.

Congress may want to take this opportunity to reiterate the importance of using reliable and relevant scientific information, which is discussed in the previous section of this testimony. For example, the Bill directs EPA to:

- Prioritize the selection of substances that pose the greatest public health concern and to identify subpopulations that are at greater risk. Section 1457(b)(2)(A). That prioritization and identification should be based on actual data that comport with minimum criteria for reliable and relevant scientific information.

- Publish guidance on procedures for developing and updating protocols, determining when testing will be required and using other scientifically relevant information. Section 1457(c)(1). That guidance should require the adherence to the minimum criteria for reliable and relevant scientific information.

- Revise testing protocols. Section 1457(d). Determining whether to revise testing protocols and revising those protocols should comport with the minimum criteria for reliable and relevant scientific information.

- Accelerate testing for substances that, among other things, are "suspected to be an endocrine disruptor or has a structural similarity to

a substance known to be an endocrine disruptor." Section 1575(e)(1). The determination as to whether a substance is suspected to be an endocrine disruptor should be determined on the basis of actual data that comport with the minimum criteria for reliable and relevant scientific information. Further, EPA is to use "scientifically relevant information" to make that determination. Section 1575(e)(2). "Scientifically relevant information" should be data that comport with the minimum criteria for reliable and relevant scientific information.

6. The scope of the Act should be clarified.

The Safe Drinking Water Act currently states, and the Bill reiterates, that a substance is subject to Section 1457 of the Act if "the substance may be found in sources of drinking water" and if "a substantial population may be exposed to such substance." The Act does not define the operative terms "may be found," "sources of drinking water," "substantial population" and "may be exposed." This language could be construed broadly as including within the scope of the Act almost any substance, even if the substance is not found in actual drinking water and even when no one is actually exposed. Indeed, an argument could be made that almost any water is a "potential" source of drinking water, possibly even an isolated aquifer under a Superfund site. Arguably, perhaps with some exceptions, any chemical may be found in such a source. Scenarios might also be imagined in which some number of people may be exposed to any water source.

Given limited testing resources, I believe it would be of greater benefit to human health to require testing of substance that may actually be expected in actual sources of drinking water. For purposes of prioritizing EDSP screening and testing, it would also be beneficial to focus first on more significant exposures. For these reasons, I believe it would be beneficial for the Bill to better define these terms and focus more on actual exposures or realistic exposure scenarios rather than what could amount to an highly unlikely chance of exposure. I believe the Bill should be modified to limit the scope of the Act to more likely drinking water contaminants. This could be accomplished by more narrowly defining the terms outlined above.

Again, I thank the Subcommittee for inviting me to testify on this very important Bill.