

Pharmaceutical Disposal Advisory Group Meeting #6

Date: June 24, 2010

Time: 9:00am – 12:30pm

Location: TCEQ Austin, Bldg E, RM 201S

Minutes

Sign-in took place from approximately 8:30am to 9:00am.

TCEQ Study Team staff in attendance: Jessica Huybregts, Eric Beller, Angela Curry, Shannon Herriott, Tom Harrigan, Daniel Ingersoll, Michelle Bacon and Jeff Horvath.

Today's Powerpoint presentations will be available on the Pharmaceutical Disposal Advisory Group webpage by July 8th

http://www.tceq.state.tx.us/permitting/water_supply/pdw/pdagroup

Total Attendees: A total of 56 people attended in person (including TCEQ staff) and 19 people attended via LiveMeeting and/or teleconference, for a total of 75 participants.

See list of attendees (in person and LiveMeeting/phone participants) on the webpage listed above.

Time: Event

9:00am: Meeting called to order by Jessica Huybregts (hereby JH).

Opening remarks and welcome by JH.

JH re-introduced the objectives of Senate Bill 1757, which are to study: the methods currently used in Texas (by consumers, health care providers, and others); alternative methods used, including methods used in other states; and the effects on public health and the environment of the various methods used for that purpose. The report must also provide an analysis of the feasibility of implementing the recommended disposal methods on a statewide basis.

JH presented a slide with the agenda for today's meeting.

Introductions were made by each participant, both onsite, LiveMeeting, and on teleconference.

JH reminded attendees that the speakers for today are those individuals who submitted requests will give presentations as part of the Expression of Interest sent out in early May 2010. Speakers will be afforded their allocated uninterrupted time and we will allow questions and comments from others if time permits. Please keep in mind that TCEQ staff will organize and moderate the speaker sessions, but the views expressed in the individual presentations will be those of the individual presenters, not the TCEQ.

9:15: Guest speaker: Mary Staples, representing the National Association of Chain Drug Stores (NACDS) & Texas Federation of Drug Stores (TFDS). For a PDF of Mary's powerpoint presentation, see the "Information from Recent and Upcoming Meetings" section of the Advisory Group webpage: http://www.tceq.state.tx.us/permitting/water_supply/pdw/pdagroup.

NACDS represents 154 pharmacies (traditional chain stores and drug stores within supermarkets) nationally. There are 25 chain drug store companies that operate over 3600 pharmacies. TFDS represents 14 chain pharmacies in Texas.

We are a highly regulated industry already. The following federal and State agencies regulate the industry: Drug Enforcement Administration (DEA), Food & Drug Administration (FDA), Centers for Medicare & Medicaid (CMS), Texas State Board of Pharmacy (TSBP), Texas Department of Safety (DPS), Texas Health & Human Services Commission (HHSC), Texas Department of State Health Services (DSHS). We already have many agencies overseeing our operations and making sure we dispense medications in a safe and effective manner.

Pharmacies currently properly dispose of drugs. We do not have unused medications in our pharmacies. We have saleable and non saleable drugs that, for different reasons, are returned to either the manufacturer (if they are saleable and can be sold to another pharmacy), or returned to reverse distributors or wholesalers and are properly disposed of. Our drugs within the supply chain are properly disposed of. These products are not the source of medications in the water supply. This is an important factor for this group to understand. The pharmacies do not encourage or flush drugs down the drain/toilet. We have to account for every medicine that comes in and out of that pharmacy.

It's important for this group to focus on 2 components (1) education of the consumer regarding proper disposal of their drugs, and (2) the actual return process for the appropriate discarding of the unused medications.

Pharmacies are very concerned when the focus starts to be on mandating that pharmacies take back these drugs into our stores because of the potential introduction of a hazardous waste product into a pharmacy. We don't know where these drugs go once they are dispensed to the customers. They could, when they're returned, be contaminated with infectious diseases or hazardous materials. The pharmacies are not designed to store the drugs within the

pharmacy with the current system, the way they are organized; there is just no space.

The question at hand is how we can help facilitate the education of consumers so they know what to do with their expired drugs. We want to help them because they come to us with these questions. We believe there are 3 key principles for the return and disposal of consumer's unused drugs:

- (1) Protect Patient Health and Safety:
 - Maintain a physical separation between pharmacies and locations that take back consumers' unused drugs. Pharmacies can't take back consumer's controlled substances. However, most consumers can't distinguish between a controlled and non-controlled substance, so the separate return facility must be overseen by law enforcement.
- (2) Ensure a Safe System
 - Provide consumers with a safe and effective way to return their unused drugs.
- (3) Ensure a Cost-Effective Systems
 - It must be a no or low cost for consumers.

There are some other added considerations. We are limited to what we can do as pharmacies because of regulations and logistics. Some pharmacies may want to voluntarily take back drugs, as was described at the last meeting, but most pharmacies don't want to be mandated to do so and they may not have the facilities to do so and they can not take back all of the drugs. So it's really not going to solve the root of the problem.

The policy options that we hope we can continue to partner with you on is finding a workable means for consumers to dispose of unused and expired drugs. Some notable programs from across the country:

- (1) White House Office of National Drug Control Policy
 - Updated guidelines for disposal of drugs not labeled to be flushed.
 - Mix drugs with undesirable substances.
 - Seal in non-descript impermeable containers and dispose of in your household trash.
 - List of 27 drug products that should be flushed (due to diversion and poisoning concerns).
 - NACDS has been advocating this program because it's the only program that has been sanctioned as the way to dispose of consumer's drugs.
- (2) Pre-paid mail back envelopes

- It takes the responsibility away from the pharmacy. Consumers can pick the envelopes up at the pharmacy, post office, for example, and place their drugs in the bag and mail it back to law enforcement.

(3) Pilot programs or collection events held in community settings.

- They are popping up all over the State.

(4) Education Programs

- The District of Columbia Board of Pharmacy is partnering with retail pharmacies to design an education program for consumers. Will use the pharmacies to get the message out. Will also have a second approach involving law enforcement.

Maine: For many years they have had Federal grants for provide funds for a consumer mail-back program, at no cost to the consumer.

Indiana: They have had a very successful Household Hazardous Waste (HHW) Grant Program. Funding is through Hazardous Substances Response Trust Fund and Solid Waste Management Fund, and it includes funding for pharmaceutical waste. Under the program, consumers can drop off unused medicines at solid waste management facilities or appropriate locations. There are federal monies out there to fund these programs.

In Texas, as of January 1, 2011, pharmacies will be required to provide the notice ***“Do not flush unused medications or pour down a sink or drain”*** on the prescription label or on the accompanying packaging (HB-19). We believe consumers will start being a bit more aware because of this.

Texas pharmacies do want to partner with you to raise consumer awareness of community collection programs and to provide guidance to consumers on the most appropriate way to disposed of unused drugs (as recommended by the FDA).

In conclusion, pharmacies do recognize the problem (that there must be a mechanism in place for consumers to properly dispose of their unused medications, both to prevent incidences of drug diversion and misuse and to minimize the impact of unused products on the environment) but we must develop programs that continue to keep the drug supply safe. Thus, there must be a separation from where the consumer picks up their medications and where they potentially bring back their drugs for disposal, and law enforcement needs to be engaged in this. Questions are welcome. You can also contact myself or Ronnie Volkening, who is with the Texas Federation of Drug Stores in the Austin area. (Contact information: Mary Staples, Regional Director, State Government Affairs, National Association of Chain Drug Stores, 817.442.1155 office, mstaples@nacds.org. Ronnie Volkening, Texas Federation of Drug Stores, 512.472.8261 office, volkening@txretailers.org.) Thank you.

Question from Eric Beller (TCEQ): Do you know if the HB-19 (requiring “do not flush” label) excludes the 27 drugs that the FDA recommends that people should flush?

Response from Mary Staples: As I understand the regulations, the Texas State Board of Pharmacy will not require pharmacies to put the “do not flush” words on the containers or packaging for those 27 drugs.

Question from Krista Crockett (Texas Pain Society): For the D.C. program, it included that they would take back controlled substances?

Response from Mary Staples: Law enforcement would be doing a collection for the mayor’s office. Unused drugs would not be going back to the pharmacies. Substances would be going to law enforcement.

9:25am: Guest speaker: Bruce Lott, Director of State Government Relations for Mylan.

Mylan is one of the worlds leading generic pharmaceutical companies; it is the largest in the USA. Mylan provides products to customers in USA and more than 140 countries. One of Mylan’s manufacturing sites is in Sugarland, Texas.

Generic drug manufacturers do have some concerns about various programs that are proposed in the USA. We support voluntary efforts to provide a mechanism for consumers to have access to safe and effective means to dispose of unneeded and unwanted drugs, but we do have some concerns about how those types of programs might be set up. A number of States do have existing drug disposal programs in various forms. Many have community-based drop off days (e.g. New Jersey), pharmacy-based take back programs (e.g. Iowa Pharmacy Association, CVS in Rhode Island), drop-off programs (e.g. North Dakota has a successful program involving police, that’s run by the attorney general’s office that has been relatively inexpensive for them to operate. Most States do appear to have at least one or more of these programs. Several States have considered mandating that manufacturers fund for take back programs. This type of a program is extremely concerning to generic manufacturers.

Washington, Minnesota, Maine, Maryland, Rhode Island all considered legislation this year that would have mandated that manufacturers fund these programs. We (Mylan) obviously have concerns for a variety of reasons. Generic manufacturers operate in a hyper-competitive market and price is intensely negotiated, leaving only razor thin profits. We could not absorb the cost of mandated programs and would be faced with 2 options (1) pass on the cost to the consumer (extremely difficult thing to do in the generic market place) or (2)

decline to sell your products in a State that mandates that manufacturers pay for take-back programs. Neither one of these is a desirable outcome for generic manufacturers or consumers. As a result, we are anxious to try to find a mechanism for dealing with this that doesn't take the mandated route.

Of the States that did consider these mandated programs this year, every one either rejected it, declined to pass it, or the sponsor withdrew it. A key reason for the high cost of take back programs as proposed is that there is an issue with taking back controlled substances. Maine, which does have a program for mail back is not state-wide and is funded by mostly Federal and some State money. They determined that it costs at least \$5 per envelope. They are not large envelopes; they won't be able to bring that more than 1 or 2 bottles of pills. There are some estimates that show that the program cost at least \$17 per envelope; though the State says \$5 to \$7.

None of the legislation proposed would have mandated that consumers participate in the take-back program; they would have only mandated that the program be created. As a result, you would have a very costly program created that would likely have little or no impact on the drugs flushed, put in landfills or kept in medicine cabinets. Proponents of the legislation have generally agreed that more than 90% of drugs found in the environment are those that have been excreted by patients and that less than 10% are a result of disposal of unused drugs. So even if we created and funded a program it would be removing only a very small amount of pharmaceuticals in the environment but at a very high cost. That is one of the issues that needs to be looked at closely. Thank you. Questions welcome.

Question from Jeff Jacoby (Texas Campaign for the Environment): What were Mylan's profits in 2009?

Response from Bruce Lott: I do not know that information. I work in government relations.

Response from Jeff Jacoby: It's over \$200 million.

JH thanked Bruce for taking the time to speak with the group today.

9:35: Guest speaker: Trish O'Day, University of Texas School of Nursing.

Good morning. I want to take 5 minutes to tell you what we're doing in the curriculum at the School of Nursing and also about an initiative that we have going on with the City of Austin.

A couple of years ago I approached Janet Pichett, our City of Austin epidemiologist and said let's use nurses as a way of disseminating information

for how to correctly dispose of unused and leftover medications. When we started talking about it we thought we could do a public awareness campaign with the City of Austin too. With our first initiative, we are incorporating into our curriculum for new nursing students (1) in general most drugs should not be flushed or poured down the drain (we have the federal guidelines and what drugs should still be disposed of in that way), (2) why (how drugs end up in the water supply), (3) the understanding that Federal guidelines change and nurses need to know how to look up the most current information, and to be aware about how take-back programs work. We added this to the first semester curriculum, and then it is reinforced when they do a teaching project in their second semester (they can use this as an example of patient education for discharge planning). We want to educate future nurses when they're in school so that whenever they come in contact with their patients in the future they can advise them how to dispose of unused drugs.

The second initiative that we're involved with (Donald Hardee from the City of Austin is here today and is one of the committee members) is public awareness for the City of Austin as a whole. We decided to not jump into a public awareness campaign but instead to survey Austin residents about how they currently dispose of their unused medications. The survey is winding up now. We'll get the results soon. Then we'll figure out next steps. We didn't want to jump into the public awareness campaign because we thought the guidance may change. Questions welcome.

Question from Selin Hoboy (Stericycle): What do you teach the nurses to do themselves with the drugs if they are providing the care and have drugs in their possession in the hospital/clinical setting that they need to dispose of?

Response from Trish O'Day: They should follow the hospital's policies.

Comment from Victoria Hodge (City of Denton): We just did a survey with the University of North Texas so I think it will be interesting if we were to share information.

JH thanked Trish O'Day for speaking.

9:40: JH noted that we are ahead of schedule. As such, we'll go straight into talking about the **pharmaceutical disposal surveys**. JH thanked those who participated in the review process. We reduced surveys to 10 or fewer questions which are designed to about 10 minutes to complete. Based on comments provided by the Pharmaceutical Disposal Advisory Group, 13 different surveys were developed for different types of activities/stakeholders that dispose of pharmaceuticals.

The 13 survey groups are: Group 1: Health-Care Provider (Patient Floor – for hospitals, clinics, ambulance services, dentists), Group 2: Veterinary Providers,

Group 3: Pharmacies, Group 4: Waste Disposal/Mgt Service Providers, Group 5: Pharmaceutical Manufacturers, Group 6: Ranchers/Farmers, Group 7: Consumers, Group 8: Home Health & Hospice Service, Group 9: Drinking Water & Wastewater Utilities, Group 10: Local Government (Solid Waste Department), Group 11: Law Enforcement, Group 12: Research Institutions and Group 13: Long-Term Care Facilities (Assisted Living and Nursing Homes).

Surveys became available to complete/submit on Monday 6/21/2010. Please complete survey relevant to you and/or distribute to your contacts in Texas, where appropriate. Please complete only 1 survey per operation (unless the methods of disposing of unused pharmaceuticals are different in different areas of the same company/operation/facility. If there are multiple people from your company on this Advisory Group they may have both received the link to the survey so you may want to coordinate with each other and nominate one person to complete the survey for the company/operation. All households in Texas can complete the Group 7: Consumer survey (1 survey per household).

Please encourage others in Texas to complete the surveys. Please remember that this is only for facilities/operations/households located in Texas. If your company does not have any facilities that manage or dispose of pharmaceuticals in Texas please do not complete the survey.

Both the instructions for completing a survey and the link to the online survey are contained within a PDF that was emailed to stakeholders on Monday 6/21/2010 and Tuesday 6/22/2010. You can also access all surveys from the TCEQ

[Pharmaceutical Disposal Advisory Group webpage:](http://www.tceq.state.tx.us/permitting/water_supply/pdw/pdagroup)

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To get to this webpage from the main TCEQ webpage (www.tceq.state.tx.us), select "Rules" in the left side column, then select "Rulemaking Advisory Groups", then select "Pharmaceutical Disposal Advisory Group (SB1757): which will be the fifth group in the list. When sending the survey to your contacts, you can either send them the PDF you would have received from JH via email, or simply send them the link to the webpage.

Surveys should be completed by close of business July 16th. (The results will be analyzed beginning Monday July 19th.)

JH asked if there are any questions regarding the survey. No questions/comments.

10:10: With the meeting is ahead of schedule JH asked for any comments or questions at this time.

Comment from Ed Gruber (Texas Health Care Association): This comment is mine personally. I think the speaker from Mylan made an excellent point that I tried to bring up in my presentation last meeting and I think that it's something that this group needs to truly understand, which is that the vast majority of drugs

in the water supply are not from flushing of whole drugs, they are from human waste. Every medication that an individual swallows has to come out either in its original form or as a metabolite. There are cases where the metabolites are more toxic than the original drug. Nothing is going to change that but altering what we do with unused medications. On another personal note, I want to defend Mylan. This is a capitalistic country and Mylan has the right to make a profit. Just because they make a profit it's not a reason to penalize them.

Comment from Lori Woznicki (Drugs and Medical Devices, DSHS): The biggest concern that I saw from last meeting, if you're talking about a take back program, you need multiple agencies involved (DPS, DEA, DSHS, State Board of Pharmacy, TCEQ).

Response from JH: Fortunately we have been able to have representative from all of those agencies attend all or some of these meetings and provide their input.

Question from Tom Kowalksi (Texas Healthcare Bioscience Institute): What is going to be your process after you look at the surveys, the agency comes up with a draft report, then what? Can you walk us through the steps until this report is finalized and what would be the involvement of the Advisory Group in that?

Response from JH: When we leave today we'll wrap everything up; the meeting minutes, survey feedback and your written comments. At this stage the TCEQ Study Team is writing the report. We will submit the report to the legislature by December 1st, 2010. After this meeting and the close of the written comment period, there won't be further interaction with the Advisory Group stakeholders before December 1st. As noted in most of the previous meetings, the Advisory Group was set up to provide the TCEQ Study Team with the information we need to incorporate into the report; to get the right people in the room to discuss this topic so that the TCEQ Study Team can write a comprehensive and accurate report. The Advisory Group is not writing the report and they will not be reviewing the report. After the report is provided to the legislature they will make decisions as to what recommendations they accept or further work to be done.

Question from Tom Kowalksi: When will you post the report after you deliver it to the legislature? When will it be available for public viewing?

Response from JH: I do not know if it will be available for public viewing. Jessica requested Isaac Jackson (TCEQ Intergovernmental Relations) provide further information on that.

Response from Isaac Jackson: Once we provide it to the legislature, I'm sure it's a public document.

Comment from Chief Mike Gentry (Texas Police Chief's Association): I realize that everyone has an interest in this. A couple of times this morning I've heard the necessity to have law enforcement involved in this and I don't think that any police chief or sheriff in the State of Texas would deny that we would need to be involved because of the possession and diversion issues. But, I would like to everyone to understand that we have a concern of our involvement morphing into a responsibility to dispose of these drugs. We are concerned about unfunded mandates.

Question from Tony Bennett (Association of Water Board Directors): I know that you have a specific charge and there are things that you can and can't put in the report, but will the excretion versus disposal issue be included in the report if it's not a specific charge of the Bill? It appears to be a significant overriding issue. What latitude do you have to include those issues in the report?

Response from JH: I think that the excretion versus disposal argument or data gap falls into the third objective of Senate Bill 1757, in considering the effects of the disposal methods on public health and the environment. Whether a disposal option will even impact the environment must be discussed in the report in order to fulfill that objective.

Comment from Selin Hoboy: One of the things that continues to resonate with everybody is the issues with controlled substances. I know that it's not something that we can control here because it's a D.C. issue. Is there any thought about putting additional pressure on the legislators to bring this issue up to D.C. I know that Lamar Smith was involved with co-sponsoring the Federal Bill, but a lot of these things are not going to go away, the need for involvement of law enforcement is not going to go away until DEA changes that statute.

Response from JH: I don't think it's our place to put pressure on legislators because Senate Bill 1757 is a study. However, I think that those issues need to be discussed in the report. The controlled substances act may be an impediment to the feasibility of adopting alternative disposal methods in Texas and that therefore must be discussed in the report.

Question from Trish O'Day: Who is the author of the report? Is it the stakeholders or TCEQ?

Response from JH: The author is the TCEQ. The Senate Bill required the TCEQ to study and make recommendations. As a background for those who may not have been involved throughout this entire process, the TCEQ Study Team decided to develop the Advisory Group to help us get all the relevant stakeholders taking about the issues and to convey to TCEQ the advantages and

challenges with methods of disposing of unused pharmaceuticals from each stakeholder's perspective so we could write a more relevant and accurate report.

Question from Trish O'Day: If the report does contain some recommendations to look at what can we do about the excretion of drugs into the water supply, could there be some recommendations that there are some incentives for water treatment plants to develop new mechanisms to filter out trace contaminants such as pharmaceuticals.

Response from JH: Thank you for your comment. We will take that into consideration when writing the report.

Comment from Jack Ranney (LCRA): It seems the lack of reliable data needs to be addressed before methods are recommended or anything is mandated.

Comment from Jeff Jacoby (Texas Campaign for the Environment): I would like to second that. There's not a lot of peer-reviewed data around. I would be interested to see if the State of Texas found other results.

Response from JH: Thanks. I think we also need to keep an eye on EPA (who are working on removal technologies, and have many grant projects underway regarding pharmaceuticals and personal care products) and also USGS (who is looking at source characterization).

Comment from Bruce Lott (Mylan): There is legislation pending before congress that would create a study to determine whether there are treatment systems for wastewater plants but that legislation has not had progressed any further. Maybe some in this group would want to encourage their members of congress to take a hard look at.

Response from JH: There are other published studies out there that tell us what treatments can remove considerable amount of trace contaminants but at this time they are not cost-effective.

With no further questions or discussions, JH announced a break for refreshments.

10:45: Reconvened following break. JH introduced next speaker Doug Finan who is representing both the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Industry Organization (BIO).

10:45: Guest speaker: Doug Finan, Director of Environmental Health and Safety, Glaxo Smith Kline (GSK), representing Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Industry Organization

(BIO). For a PDF of Doug's powerpoint presentation, see the "Information from Recent and Upcoming Meetings" section of the Advisory Group webpage: http://www.tceq.state.tx.us/permitting/water_supply/pdw/pdagroup.

I started with GSK in 1990, doing environmental assessment for drug products. Since the 1980s, every time we submit a New Drug Approval application to the FDA we're required to submit an environmental assessment that considers the impact of use, disposal and manufacturing on the environment. This is part of the National Environmental Policy Act.

Our companies are committed to using the same scientific approaches that we use in all aspects of our company to look at what may or may not be the environmental impacts of our products.

Our research is focused on 3 areas: Human health impacts of pharmaceuticals in the environment, the impacts on aquatic life, and unused drug disposal. The goal is to be part of the scientific discussion so we try very hard to use peer-reviewed publications to get the information out when we do the science. We have supplied a lot of those publications on a CD that I provided to TCEQ.

We've also tried to work in collaboration with lots of different agencies (USGS, EPA, FDA, European agencies).

When we talk about using a scientific approach, we're really talking about taking a risk assessment approach. The fact that you can detect something in water doesn't necessarily mean that it is a problem. Our entire environmental regulatory system is based on identifying safe levels of substances in water and allowing permits to be written to those safe levels.

The results of our human health assessment indicate that the residues of pharmaceuticals in water represent no appreciable risk to human health. Yes, you can find pharmaceuticals in water and drinking water but they're not going to present a risk to human health. To put it into perspective, in Eerie, PA, they found 2 parts per trillion of ibuprofen in their drinking water. It would take a person drinking 2 liters of water 100,000 years to get a single dose of a 200 mg tablet through consumption of that water.

We also looked at aquatic life impacts of pharmaceuticals in the environment. We found that the concentrations of pharmaceuticals that are typical in environmental settings are not high enough to cause the types of effects you can see in experimental settings. We recognize that the science behind understanding the aquatic impacts is still developing (e.g. impacts of exposure to long term of low doses). PhRMA members are participating in that development.

We have been hearing a lot about pharmaceuticals in water. You've probably seen the feminization of fish studies and these are mainly studies on synthetic hormones. Ethinylestradiol (EE2) gets the worst reputation here. So the pharmaceutical manufacturers did some science on EE2 in particular. The first thing they found was that the measurement system is a little in error. They were measuring more EE2 out there than is even manufactured, so the industry researchers needed to first figure out why that is the case. They found that there are some impurities in the analysis. When you throw away all the results that weren't done with tandem mass-spectroscopy and other best available technology, all the detected values falls into the realm of reality. So something to point out is that you can't always immediately believe the data; you must consider what method they used in their analysis to be able to interpret data correctly.

There are some pharmaceuticals that exist in the environment but are at levels too low to detect with the current analytical methods. PhRMA is working with EPA to get the PhATE model validated that could help predict environmental concentrations for those types of compounds. When you model EE2, you find that the predicted "no-effect" concentration (PNEC) is higher than the predicted environmental concentration (PEC). What does this mean? Does it mean that we haven't seen those aquatic life effects? No, it means that it's not just EE2 alone. There are lots of endocrine disruptors out there that in combination may impact aquatic life.

Having set the scene, here is some key information related to disposal of unused pharmaceuticals. The main source of pharmaceuticals in the environment is patient use. No matter what we do with unused medicine disposal, patient excretion will still continue to drive the situation of pharmaceuticals in water. We also found that disposal in landfills is effective and environmentally acceptable. Flushing should be avoided, when possible. Take back for incineration is not the most effective product stewardship approach. Long term care facilities (LTCF) will require different approaches than the general public.

Landfill Information: We assume that 10% of pharmaceuticals go unused. There are few studies in the peer-reviewed literature that quantify amount that goes unused. Two studies in LTCFs estimated about 10-13% of drugs go unused in that setting, and on the consumer side estimates are around 2-3%. You might also hear the number of 35% for the proportion of unused drugs that go unused in the household (published by the Teleosis Institute). As a cautionary note, this may be overestimate due to how the information is gathered – they estimate what proportion of pills in a container (that they received back) compared to what the container says was originally there. The data collection, therefore, does not take into account the drugs that are completely used (no container would have been returned). So to average out the LTCFs (10-13%) and consumer (2-3%) we'll assume that about 10% of drugs go unused by patients.

If all unused medications were flushed, human use would account for about 88% of pharmaceuticals in water. If all unused medications were placed in a Subtitle D compliance landfill, about 1% of pharmaceuticals end up in the water.

EPA also worked on pharmaceuticals in landfills. They conclude that landfills contribute a negligible amount of pharmaceuticals to the environment.

Maine landfill study: For all pharmaceutical compounds tested, except one, the concentrations that PhRMA's model estimated would occur in the landfill leachate were higher than the average concentrations detected in the Maine investigation.

Product Stewardship approach:

1. Don't generate the waste in the first place.
2. *Reuse (however, patient safety dictates that any medicine dispensed to the general public that goes unused be disposed).*
3. *Recycle (however, patient safety dictates that any medicine dispensed to the general public that goes unused be disposed).*
4. Dispose.

When we look at disposal, our options for disposal in the US:

1. Drain Disposal: we all agree that we shouldn't do that (except the 27 drugs on the FDA list).
2. Household Trash Disposal:
3. Collect for incineration: there are poor participation rates in the US.

To compare household trash disposal to collection for incineration: about 15% of trash is incinerated in the US and for take-back events participation is about 20%. When you do the science, the impact on pharmaceuticals in the environment for these two methods is very similar; patient use is still the most significant factor. Additionally, most take backs for incineration is a much higher carbon footprint, and there are controlled substances issues. It's legal to put our household hazardous waste and dispensed controlled substances in the trash because we design our Subtitle D landfills so stringently.

Because of these data, the pharmaceutical manufacturers partnered with the US Fish and Wildlife Service, American Pharmacists Association, to develop the SMARxT Disposal Program to promote not flushing drugs but instead putting them in the household trash. On top of this disposal approach we promote source reduction including educating patients and healthcare professionals as to why drugs go unused in the first place.

Drug Abuse and Poisoning Issues: From our perspective, prompt disposal is the key and the best way to do this is to put it in the trash. Additionally, diversion is just as likely to occur with active medications as they are with expired or medications that will not be used. Therefore safeguard all medicines in the home

all the time. Just having an unused medication take back program is not likely to make a difference to drug abuse/poisonings. It's more of an issue in education about how to protect your medications from unintended users.

There has been interest in the European take back programs that have been available for much longer than programs in the US. The European programs were started for different reasons (lack of landfill space etc.). Europe doesn't have the same stringent US rules on Municipal Solid Waste (MSW) landfills (Europe has a lot of unlined active landfills). Some of the European programs are funded by manufacturers, some are not. Typically participation in the programs is less than 20%. Most importantly, the European programs have not shown any (or documented any) reduction in concentrations of pharmaceuticals in water and have not shown any reductions in drug abuse or poisonings since the take-back programs came into place. However, they do not have any metrics on this.

In summary, there aren't compelling reasons why take back programs would impact public health or the environment significantly.

Recommendations for a Public Education Campaign: Education should concentrate on:

- Don't flush unused medicine.
- The proper way to safeguard all of the medicines under their control.
- Adherence and other ways to reduce the amount of medicine that goes unused.
- How to properly dispose of unused medicine in household trash.

Recommendations for Residential Unused Medicine Disposal:

- Household trash disposal is environmentally friendly and meets all DEA & EPA requirements.
- The scientific data does not support the need to develop a new program to take back & incinerate unused medicine.
- People that don't feel comfortable with household trash disposal should be encouraged to take advantage of existing programs & infrastructure.
 - Household hazardous waste collection.
 - Law enforcement evidence disposal programs.

JH thanked Doug for presenting to the group today. Questions welcomed.

Question from JH: Since the greater amount of pharmaceuticals in the environment are a result of excretion rather than intentional disposal, is there anything we could do during the pharmaceutical formulation process that would alter this (i.e. re-formulate drugs so that our bodies uptake more of the active pharmaceutical ingredients)?

Response from Doug Finan: We are doing these sorts of these now as part of the design and formulation process. We consider are the drugs safe, do they stick

around long enough to do their job and can they be removed from the body. We're doing what the science allows us to do right now. People talk about "Green Chemistry" as a solution to this, but most of the work in that area is about trying to use less toxic materials in the manufacturing process itself (less about what happens to the medicine once it leaves the body).

Question from Tony Bennett: Is there further information about what percentage of these drugs are passed through the intestinal system without being absorbed into the body compared to what is excreted?

Response from Doug Finan: Yes, I don't have the specifics with me here. (It's very chemical specific. When you do a NDA submission through the FDA, one of the things you must submit is the metabolite profile. The environmental assessment regulations require that if we have a metabolite that is more than 10% of the metabolite profile we have to consider the environmental fate and effects of that metabolite as well. Most of it is probably privileged information that only gets seen by the regulators, but yes, that information exists.)

Question from Charlotte Smith (PharmEcology, WM Healthcare Solutions): Can you explain how the environmental assessment works? My understanding is that the US is about 100 times more lenient than the European Union. Can you please explain that?

Response from Doug Finan: Environmental assessment requirements have evolved over time. Originally there were no categorical exclusions for pharmaceuticals in NEPA; you'd send in a NDA, you put in the environmental assessment. After about 10 years of doing this FDA looked further and said that if you calculate that the predicted environmental concentration is going to be less than 1 part per billion then they set a categorical exemption. They also require you to do a maximum forecasted production in a 5 year forecast. The reason for the 10 fold difference in Europe and the US has to do with the dilution factor that they (Europe) allow. My understanding is that FDA's predicted environmental concentration (PEC) is end of pipe with no in stream dilution and FDA considers a PEC/PNEC ratio of less than one acceptable. While the European Medicines Evaluation Agency (EMA) allows 10% in stream dilution to be used when calculating the PEC and EMA considers a PEC/PNEC of 0.1 acceptable. When you compare it without the dilution factor, both predicted environmental concentrations are similar.

11.30am: JH opened up the floor to all attendees for questions or comments, emphasizing that this is the final opportunity to comment in this Advisory Group setting. No questions or comments.

With no other stakeholders providing questions or comments, JH thanked all for their attendance today and for those who have attended multiple meetings since the first in January 2010. JH reminded attendees that this was the final

Pharmaceutical Disposal Advisory Group meeting, as was conveyed at the beginning of this process. At this time the TCEQ Pharmaceutical Disposal Study Team staff will be using information gathered from these meetings, surveys and literature to write the final report to be provided to the legislature (by December 1st) in response to Senate Bill 1757. If stakeholders would like to make written comments that you would like us to consider during the report writing process, please send those by email to Jessica at <jhuybreg@tceq.state.tx.us> by 5pm July 2nd. Any comments received after this date will not be able to be considered. Please keep material under 10 pages (single spaced, 12 pt font) and pertinent to the objectives of Senate Bill 1757. Please disseminate the survey links to your contacts.

11:40 Adjourn

*Minutes offered for review 6/28/2010 – 7/6/2010.
Minutes finalized 7/8/2010.*